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Laura J. Esserman, MD
Principal Investigator

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13. ABSTRACT *(Maximum 200 words)*

During the second year of the DOD grant "A New Vision for Integrated Breast Care", we have continued to design and in some cases implement unique programs and services for the benefit of the patient. Our Continuous Quality Improvement, Informatics and Education Cores are working together to help streamline implementation of programs. This enables us to identify the quality improvements we hope to gain by changing a service and the quality measures needed to capture change; to design databases and data collection forms to capture the data; and to identify the educational efforts required for patients, referring physicians and our own staff for successful implementation. The Administrative Core must integrate all of the pieces and attach a timeline. In Year 3, we will launch many of the programs which have been designed this past year: Coordinated psychosocial and satisfaction measures; the Same-Day Evaluation program; surgical and pathology standards complete with integration to the micrometastasis; sentinel lymphnode and MRI clinical trials; the Follow-up program to collect outcomes data and optimize the time of various practitioners, the adjuvant risk program; and our second-opinion service, including consultation planning, interactive decision-making and a written record of the consultation.

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FOREWORD

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Table of Contents

Introduction

Year 2 of the grant was an important step in the structural development of the Breast Care Center. We began with a re-engineering of workflow and held focus groups with patients to better understand what services and functions were of greatest value. We followed this work with restructuring of goals and time lines for all projects and cores. This evaluation was crucial in our process of refining the foundation of our work to pioneer an innovative, cost effective, single-site treatment, research and education center.

As we move towards full integration of all of our projects and services, we continue to streamline our processes and discover and define ways in which to reduce variability and duplication so that each patient at the BCC receives the same high quality standard of care. The work of our Informatics team has been instrumental in tying together all of our efforts. Our database will be a key focus during the next year to both collect and provide us with data, as we move forward with measuring outcomes and creating necessary interventions.

We have added a number of services for patients at our center during the last year, including a genetic testing and counseling program, as well as patient consultation planning and recording. The Breast Care Center clinic now occupies the entire sixth floor of the Cancer Center outpatient treatment building, while the administrative and research staff has moved to an off-campus location on 2299 Post, one block away. This enabled us to keep our entire administrative staff together.

Highlights of our Year 2 activities by Core/Project include:

Cores

The activities of the Continuous Quality Improvement (CQI) and Administrative Cores are closely interlinked. Our goal is to take a leadership role in defining the quality of breast cancer care and finding ways to reorganize services that bring better value for patients and eliminates costs from inefficient processes and interventions of little value.

This requires defining quality starting with a patient perspective; translating definitions of quality into process and outcome measures and dissecting process and outcome measures into their primary data elements so that data can be gathered in common measures at the point of care, processes of care can be better mapped, and interventions can be designed and measured for effectiveness.

Efforts included addressing the barriers to adoption of processes that deliver better quality at the same or less cost within our very large, cumbersome health care insurance system which currently does not reward change at the single-disease level.

The focus of the CQI Core was the development of a follow-up program for the collection of information that doctors and patients need to better understand the outcomes of interventions. This will enable us to make decisions about interventions, standardization of forms and procedures, availability for new patient appointments, improved efficiency, and cost effectiveness.

Working closely with the Informatics Core, we have designed a clinical database and we have begun collecting data electronically to gather baseline information so that necessary improvements can be made and monitored over time.

Quarterly meetings involving all team members continue to be held to ensure communication between all participants.

The Informatics Core has implemented most of the new work-flow and communication system, which will facilitate results tracking and will enable us to automate data realized from re-engineering our practice. The BCC front office staff has been trained on the automated intake form.

We have also designed a database of demographic and clinical data elements for breast cancer. Its structure is being coordinated with a related effort at the National Cancer Institute (NCI). Dr. Esserman (grant PI) is a member of the NCI Common Data Elements Project.

The Education Core has expanded its work on providing patients with detailed and relevant information about diagnostic procedures, breast cancer treatment options, and access to resources. They have developed information packages for newly diagnosed patients, as well as other information packages, such as for surgery patients. The surgery instructions have been standardized for all physicians and translated into Chinese. They have also developed a comprehensive library, focused on decision-making with breast cancer. Furthermore, they have established a literature bank that serves the needs of physicians, residents, patients, and patient families.

A speaker program has been established covering a variety of topics of interest to both patients and staff.

Projects

Project 1 had been significantly modified due to the merger of California Pacific Medical Center (CPMC) and UCSF Medical Groups (as described in last year's Annual Report). Patients from can now choose sites, and for this reason, a study based on a comparison of the sites is no longer valid. Instead, we are sampling women from both sites, but the analysis will focus on differences in management by the primary care provider after a report of an abnormal mammogram.

We have completed revision of the study design and finalization of all of the study instruments. Data collection is being initiated and is expected to continue throughout the next project year. The Same-Day-Evaluation program is being implemented for testing.

Project 2, the Breast Cancer Lifestyle and Personal Program, spent the second year implementing an entirely new and different program for women with breast cancer for comparison with a group representing the community standard. Data collection is underway. Initial data show that both of the interventions resulted in significant improvements in positive mood and quality of life. Despite the rigor and time intensity of the Integrated program, both of the interventions have been shown to be feasible, both for the staff and for the patients.

Project 3: The purpose of this project is to capture the patient's understanding of risk of recurrence and potential benefit of adjuvant therapy. A significant roadblock was identified as the lack of calibration of risks of mortality and recurrence prior to adjuvant therapy. In addition, agreement was required on the interpretation of several key large new studies, as well as the 1995 world overview analysis. These studies revealed significant new estimates of benefit from adjuvant therapy. We successfully completed our first "Calibration Conference" and will be using the information in software to test patient preferences for adjuvant therapy, starting this fall.

Project 4: The creation of a joint plan with the CQI Core for decision support in the BCC proved to be the most significant event of Year 2 for Project 4. This new vision for decision support, which we call Collaborative Care Facilitation, sequences two Project 4 interventions—Consultation Planning and Recording—with a third, CQI intervention, namely Collaborative Treatment Selection. By the end of Year 4, BCC patients entering the BCC will be offered visit preparation, visit facilitation, and the evidence-based analysis of treatment options. Many researchers have tackled pieces of this puzzle, but the BCC will be the first clinic to integrate them. Our goal for year 3 is to develop the next phase of collaborative care, consultation recording and the creation and recording of the treatment and decision plan between patient and physician, with the real-time generation of a summary report for the patient.

Pilot A: Our education and outreach program to patients and care providers is being rolled out ahead of schedule and more broadly than originally planned. Our baseline clinical trial enrollment is already more than double the national average. Additionally, we are focusing our efforts on minority outreach.

The tracking system developed for Pilot A has proven to be an extremely valuable tool for other aspects of patients care in the Breast Care Center. This tracking system will be modified as a more comprehensive Informatics system is implemented in the Breast Care Center.

The Bay Area Breast Cancer Forum is well established and attended. The minutes of the Forum, as well as clinical trials information, have been made available on the internet.

* * *

The BABCP has made great progress over the past year, as will be detailed in the following pages. We will continue to re-engineer the practice infrastructure and move towards the end goal, an exemplary single-site inter-disciplinary breast care center. We are confident that this center will serve as a paradigm for care delivery for the next decade.

Administration Core
&
CQI Core

Administrative Core and Continuous Quality Improvement (CQI) Core

The CQI and Administrative Cores are closely integrated. The work of the Administrative Core facilitates the investigation of the outcome measures that are an important theme within the CQI Core.

Administrative Core

There are some activities that are primarily administrative. They include:

- All outstanding subcontracts and consultant agreements have been finalized and in some cases the work completed. A close working relationship with the UCSF Contracts & Grants office has been established to ensure compliance with all rules and regulations.
- The administration and research staff has moved into off-campus facilities, and the grant has been re-budgeted accordingly with a new indirect cost rate of 26% starting 4/15/98. This was approved by the DOD Grant Officer.
- A Breast Care Center newsletter has been created and is being distributed (originally quarterly, now bi-monthly) to bring DOD grant and other issues to the attention of all team members and associates (appendix A).
- The new Breast Care Center brochure has been created to help raise patient awareness of all the integrated services available here (appendix B).
- External information standards for Breast Cancer
  ·Dr. Esserman serves on American Society of Clinical Oncology (ASCO) of Health Services Research Panel
  ·Dr. Esserman is a part of the NCI working panel whose purpose is to establish agreement on common eligibility criteria for clinical trials

CQI Core

Introduction

During Year 2 of the grant, the focus of the CQI Core was on the development of a follow up program that would enable: the collection of information that doctors and patients need to better understand the outcomes of interventions to enable them to make decisions about interventions, standardization of forms and procedures, availability for new patient appointments, improved efficiency, and cost effectiveness. Working closely with the Informatics Core, we have designed a clinical database and we have begun collecting data electronically to gather baseline information so that necessary improvements can be made and monitored over time.

Statements of Work (SOW)

We have revised the statement of work for the CQI Core to better meet the current and future needs of the Breast Care Center (appendix C and below) especially since many of the tasks in the original SOW (appendix D) were accomplished in year 1 (tasks 2,3,). Also, Task 1 is being covered by Pilot A, Task 4 is being worked on by the UCSF Center of Excellence for Women's Health (of which we are apart of), and Task 5 will be covered in this report.

Old Statements of Work:

1. Study reasons for delay in the detection of breast cancer in minority women.
2. Adopt strategies to reduce utilization of formal axillary node dissection.
3. Adopt a standardized method of physical breast examination.
4. Develop a consensus on use of hormone replacement for patients with breast cancer.
5. Work with Informatics core to get information from Clinical Information System in format that will facilitate CQI process.

New Statements of Work:
C1.1 Choose clinical and medical outcome measures to be used as the "report card" for the Breast Care Center. These measures must reflect the needs of the patients, the physicians, health plans, and employers.
C1.2 Establish patient navigator program
C1.3 Create a new follow up program
C1.4 Hold a patient a series of forums to address the issues of quality according the patient
C1.5 Identify hierarchy of values of patients and providers regarding treatment decision making
C1.6 Create survey instruments for staff and MDs to fill out regularly to identify areas where improvement is needed.
C1.7 Tracking and then identifying improvements on the time it takes to perform a wire localization procedure.
C1.8 Creating patient satisfaction surveys
C1.9 Coordination all surveys and activities

C1.1
A CQI committee (consisting of a pathologist, oncologist, nurse practitioner, surgeon, clinic manager, project manager, CQI analyst, information systems manager, consultant from California Pacific Medical Center, a patient, a consultant from the Institute for Heath and Policy Studies, Stanford team) began meeting early in the fall on a bi-weekly basis to work back through the outcomes measures packet (included in the annual report from year 1) to choose which measures should become part of the "report card" by which we will measure our overall performance. Discussions resulted in an analysis of goals and objectives from different perspectives. By thinking about who these measures would be important to, we created what we call "the food chain" (appendix E).

Three main tasks were generated:
a) Measures Research
This group has begun to survey the stakeholders (see food chain). We have just hired a consultant who will assist us in refining the outcome and process measures as well as identify where in the process of care they should be addressed.

Our first step in the process was to create an interview methodology and then conduct interviews with members of each of the groups in the "food chain" (referred to above, appendix E). This work was done by Synergia (with whom we had a sub contract with this year). The main purpose was to collect their perspectives of (everyone on the food chain) on quality in breast cancer. The scope of our work began to solidify as we sought to understand what various stakeholders value in the delivery of breast health services and to identify conflict among these perspectives. We did not see conflict as problematic per se, but rather as an opportunity for learning, Ultimately, we sought to collect data representing various perspectives to inform the selection of quality measures to be implemented at the BCC and similar organizations.

Now that many of these interviews have taken place and lists of what is important to each group has been created and prioritized, we plan to take this information and use it as we decide which outcome measures we will use to monitor our overall improvements.

b) Measurement Development
Within the CQI core, a subcommittee led by Dr. Wade Aubry was formed to help define the direction of our CQI end product and create a "report card" which will consist of performance measures related to breast cancer care. The data set will reflect a clear understanding of the relationships between the many stakeholders in health care purchasing (such as health plans, employers, public agencies, consultants, and patients), and the project will have an impact on how

quality measures are reported and integrated into systemic improvement. The "report card" is the evidence-based rating of our various services which can be evaluated by any or all of our stakeholders.

Dr. Aubry and the subcommittee have been focusing on the actual building blocks of the "report card". One measure that is currently being tested is the rate of re-excision after an excisional biopsy or lumpectomy. Patients are interested in this information as a way to evaluate the quality of surgery performed at a breast care center. Health plans want to know about re-excision rates not only as a measure of quality but also to help determine costs for treating their members with breast cancer. Another example is a measure of the effectiveness of disseminating information to patients regarding treatment options following a diagnosis of breast cancer. These measures are currently in the process of being tested, and other measures will also be considered that are relevant to the various stakeholders

A key issue in performance measurement is how quality can be used to drive purchasing decisions by the various stakeholders. In the current environment, these decisions are made almost entirely on the basis of cost. If a data set of measures representing the spectrum of breast cancer care is developed and adopted as a valid assessment of quality, then the potential exists for this information to leverage contracts and provide positive incentives for further improvement in patient care. This would be beneficial to the providers of care as well as the various stakeholders.

c) Clinical Group
This group meets weekly to identify, prioritize and implement CQI projects that focus on day to day activities in the Breast Care Center. For example, one project currently underway is a billing form completion study. Its purpose is to track the number of missing encounter forms by provider by the end of the day in order to identify problems in the system that need to be evaluated and changed. Our goal is to give feedback to physicians so they can improve accordingly. And in fact, so far, there has been a considerable improvement (appendix F).

C1.2
Currently a patient navigator program is being developed; this pilot program begins as of July, 1998. This program has been created to help women cope with and manage the many challenges they face once they are diagnosed with breast cancer. The objective is to match a former breast cancer patient with someone newly diagnosed to help them navigate through the clinic and help them cope with the many issues that arise during this time. Carrie Sanders, the CQI analyst, is involved in developing this program in order to receive feedback from the navigators on what areas they feel need improvement. We have also created a project arm, as part of the program, which allows patients to get involved in various project which focus on improving the care we provide (see appendix G for training manual).

C1.3
In an effort to provide advanced training in quality management, Carrie Sanders, CQI analyst and Laurel Bray, the BCC practice manager attended and successfully completed a course, Quality Management in Health Care at Stanford University School of Business this Spring. As part of the course, a quality improvement project was undertaken at the BCC. Their project focused on improving the follow up system at the BCC (follow up refers to patients who have finished active treatment). We found that our current system is inefficient due to: variations in care, the number a follow up visits a patient has, duplication and other inefficiencies. We have gained an understanding of what is currently done by each physician at the BCC, by gathering baseline data, researching what information exists in the literature and by inquiring about other programs at other breast centers around the country (appendix H). A major improvement was to identify the follow up visit as a critical time point in which to collect important data to generate patient centered care outcomes (e.g. lymphedema rates, satisfaction with choices, mobility issues after reconstruction,

etc.). This effort will be continued into year 3 and we plan continue to design and then implement the new program within the year.

C1.4
In May a patient forum was held which focused on quality according to the patient. Oftentimes care providers, insurance companies, and employers assume they know what is important to patients. We feel it is extremely important to go directly to the patients to get this vital information (appendix I). We plan on using the feedback we received to direct CQI projects and plan to hold more of these forums in the future.

C1.5
As a part of our effort to integrate the services we provide at the BCC, we have developed a service we call treatment selection. This methodology we have created involves obtaining information that pertains to a patient's treatment decisions. This will give providers the opportunity learn more about what patients value most when making decisions about their care, and at the same time, allow us to use the information to help patients make better decisions given their individual situation.

(See diagram on the next page)

The bold arrows indicate the way the medical process currently operates. The non-bold arrows indicate the additions to the current process that our project envisions and has operationalized.

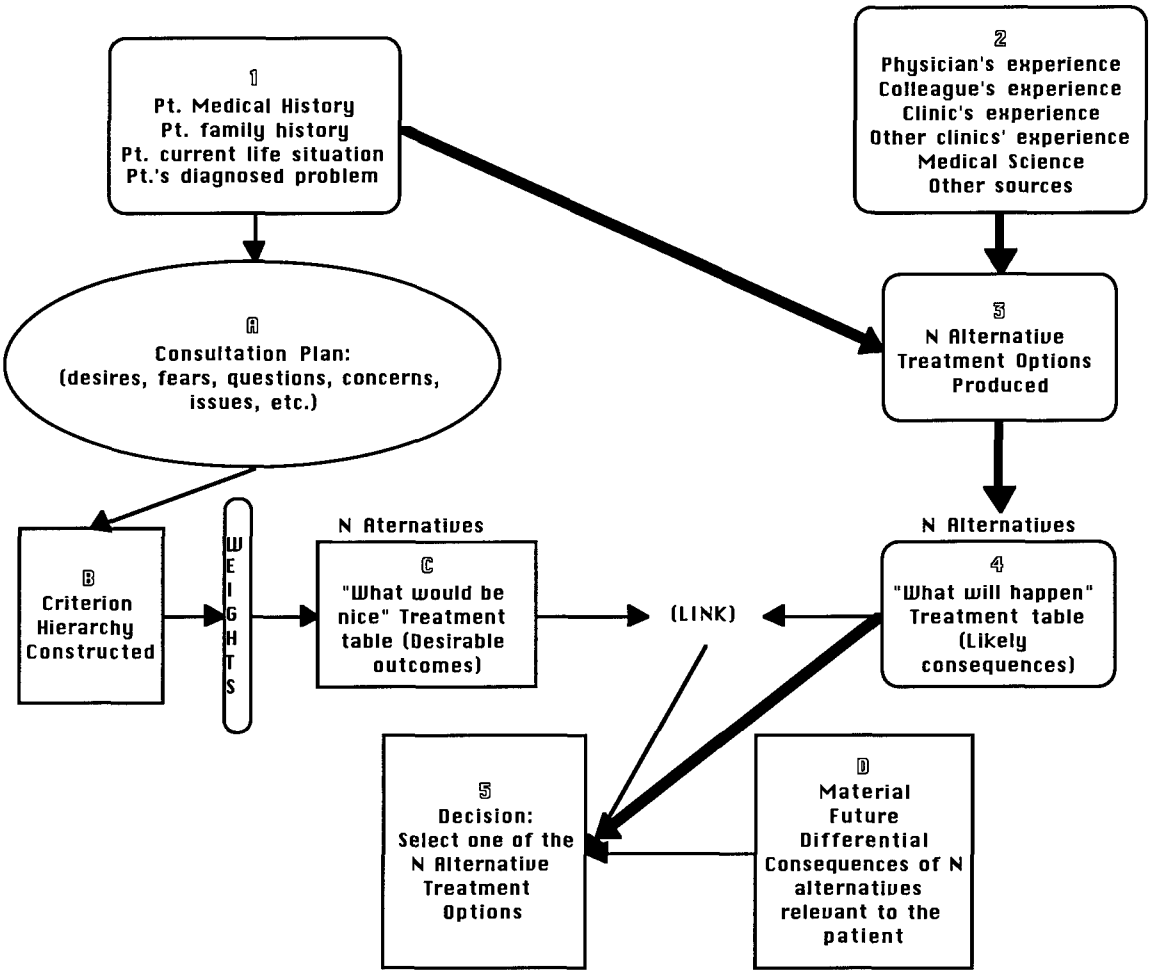
Box #1 describes what the patient presents about herself. The presentation consists of the various items included within box #1. Then the physician, drawing from his/her personal experience, his/her colleague's experience, the clinic's experience, other clinics' experience, medical science, and other sources at hand (see box #2), produces N alternative treatment options for the given patient (see box #3). The likely consequences of each alternative treatment option are discussed among colleagues and then with the patient (see box #4). Based on these discussions, one of the N alternative treatment alternatives is selected and implemented (see box #5).

Box A describes the Consultation Planning Process (project 4) wherein the patient's desires, fears, questions, concerns, issues, etc., are clarified and mapped. From this is constructed, in the form of a hierarchical tree, explicit criteria by which the patient will evaluate treatment outcomes (see box B). During a focused interview the patient assigns her relative importance weights to the criteria in the hierarchical tree (see box C). The next step is to combine what will happen to the patient (as indicated in box 4), like it or not, under each of the N alternative treatment options with what the patient would like to have happen (as indicated in box C), whether or not it actually will happen. This results in a final decision. One of the N alternatives options is selected and implemented.

Box D summarizes the discipline that our procedure, combining traditional medical practice with our additions to the current process, brings to bear upon the final decision.

- The decision is based on a comparison of the consequences of choosing one of the N alternative treatment options.
- Only future consequences of actually selecting one of the treatment options are considered.
- Only differential consequences among the N alternatives are taken into account in making the final choice.
- These include only material consequences relevant to the patient.

Our additions to the current process (see boxes A, B,C,D) have been operationalized in the form of a sequence of structured interviews and embodied in accompanying software.



C1.6

In order for CQI to be successful in the workplace one must first promote team interaction and dispel fear. Regardless of the employees' position, it is important to ensure that everyone's opinions and contributions are of equal value. To facilitate this we have implemented a system by which we periodically give surveys (appendix J) to the front office staff and clinicians which ask them to evaluate each other in order to identify communication barriers so we can help them to work together to solve any problems; what sometimes looks like conflict, might be on further analysis common interest and the surveys might be useful to at least recognize that fact. We have recently distributed the first round of questionnaires and will continue to track the results. Our hope is that this helps break down any unnecessary barriers and feelings of inferiority or resentment. If no improvement is found we will concentrate on developing an alternative approach.

C1.7

Fine needle localization is a procedure which requires the coordination between three departments: Radiology, Surgery, and Pathology. In the current system, the patient goes to Radiology to have the needle placed and is then sent to Surgery for the removal of the suspicious radiographic findings. Pathology then examines the tissue and gives the final diagnosis to the surgeon who then relays the information and next steps to the patient. The measure of quality for the patient is defined by the amount of time spent during this whole process. The purpose of this investigation was to identify the degree of variation in procedure times for each of the different stages of the fine

needle localizations, identify correlations between variables and time as quality measures, and to formulate hypothesis on potential special causes.

The study was divided into 3 sections: Radiology, Surgery and Pathology. The radiology procedure was subdivided into 6 distinct steps that were measured in increments of time. We were able to perform a retrospective study of over 1300 patients over a time span of 10 years. The statistically significant findings were:

1) Specific institutions and referring physician had an impact on the time from when the patient realizes she needs a fine needle localization to the time the exam could be scheduled.
2) Specific institution and radiologists had a significant impact on the patient wait time once they arrived for the procedure.
3) Specific institution, specific radiologists, and the presence of a second radiologist during the procedure had a significant effect on procedure time.
4) Specific institution and radiologists had statistically significant different wait times for when the procedure is completed to the time the patient leaves the radiology suite.
5) Specific radiologists had an impact on the time it took for the exam to be transcribed.

The same type of study is being implemented in the Surgery and Pathology section of the study. We are currently collecting time flow data. Due to the small sample size, no meaningful conclusion can yet be drawn. One of the next steps we plan to take is to reapproach the physician who represented the largest difference in order to research the situation further. This project was researched by Rich Lin, MD who is currently enrolled in the Stanford School of Business. He took the Quality Management course along with Carrie Sanders and Laurel Bray (appendix K are his slides from the class presentation).

C1.8

Patient feedback and involvement in the development of the Breast Care Center is critical. One way in which we have begun to assess patient satisfaction is through a survey we distribute to each patient (appendix L) at the time of the visit (there is one for new patients and one for follow up patients).

C1.9

The patient satisfaction survey mentioned above, only gives us some feedback, we want to make sure that we see the whole picture. There are many projects in progress at the BCC, each of them asking the patients to fill out various different questionnaires. We want to coordinate them in order to avoid duplication. It is important to make sure that we integrate these programs so the pathway for patients is smooth and consistent. By using a flow chart to illustrate the process at the BCC so we can understand how to link things together to gather the information we need to provide the best care (appendix M).

Conclusion

There have been a few personnel changes over the past year. Cheryl Gelder-Kogan, Cancer Center Practice Manager, has left the Cancer Center and has been replaced by Cathy Garzio. Cathy, a senior UCSF Practice Manager, was also involved in the implementation of PACE, the new business information system installed across the Clinical Enterprise at UCSF. Her role was to represent practices, physicians and staff who will need to use the system, in order to make it more user/patient-friendly. Her experience will be invaluable as we continue the work of this core. Sarah Paris has taken over as Grant Coordinator as Carrie Sanders is now the CQI Analyst. We have completed our contract with Synergia and the additional funds will be used to support the CQI Analyst and Informatics support.

In year 3 of the grant we plan to focus on the following tasks:

1. Implement F/up Program- measure the impact
2. Implement Same day Dx Clinic-measure the impact
3. Continue Surgery Tracking Sheet Project- identify areas where there is variation and create interventions and then measure impact 3 months later
4. Work with Informatics Core to develop clinical database and ways to collect critical information.
5. Refine the outcome measures list and use it to report measured improvements
6. Make sure that every project underway at the BCC has a mechanism in place for measuring improvements and identifying problems.
7. Implement Treatment Selection and continue to collaborate with Project 4.

Informatics Core

Informatics Core

Introduction/Summary/Statement of Work

The Informatics Core continues to focus its efforts on defining the critical data elements necessary to the day-to-day process of caring for patients with breast disease. We have accomplished this by developing and supporting medical informatics projects in collaboration with other Cores and Projects of the Bay Area Breast Care Program (BABCP).

In last year's report, we mentioned our plans to standardize and automate patient intake forms, as part of a Clinical Communications System (CCS). As described below, we have accomplished this task. Automation of other processes within the Breast Care Center (BCC) is still under evaluation for inclusion in the CCS, as will be discussed.

We have developed several databases for investigators in this project. A clinical trials eligibility database is now in use by Dr. Debu Tripathy and colleagues. We have also designed a database of demographic and clinical data elements for breast cancer. Its structure is being coordinated with a related effort at the National Cancer Institute (NCI), and with other UCSF breast cancer databases mentioned in last year's report. Dr. Esserman (grant PI) is a member of the NCI Common Data Elements Project.

The Informatics Core has also developed a publicly accessible Web site for use by patients and clinicians.

We have continued our collaboration with, and support of, other cores and projects. We are working closely with the CQI Core to provide them with data, collected from our automated systems, for outcomes analysis. We are also working with the Psychosocial Core to automate their data collection process.

Finally, we are continually evaluating information systems that could improve our efforts to automate the BCC.

Task 1: Development of the BCC Clinical Communications System (CCS)

Working with the medical software consulting group, Health Connection, we have developed software to automate the process of patient intake in the BCC. This component of the CCS provides an online intake form that automatically downloads patient demographic information from the UCSF Medical Center's registration system. The BCC office personnel enter additional patient intake data using the Web browser, Internet Explorer. All data are stored in a Lotus Notes/Domino database and are electronically searchable. Automating this part of the BCC has had the beneficial effect of reorganizing and streamlining the patient intake process, but it has also underscored the difficulty of computerizing the complex process of providing patient care. Indeed, users of the patient intake system have found that computerized data entry can be more time-consuming than using manual intake forms. During the coming year, we will continue evaluate the benefits (e.g., online searchable electronic data) versus the limitations (increased data entry time) of the automated intake system.

Health Connection has also developed software to automate the process of scheduling patients for surgery. Using integrated workflow software from ONEstone Information Technologies, this component of the CCS could route patient information automatically to individuals and departments responsible for many aspects of surgery scheduling. We have not implemented this component,

however, because of the complexity of the underlying software. We will continue to assess this system during the coming year.

We are continuing to evaluate other technology to enhance the CCS. The UCSF Cancer Center intends to adopt Oracle as the standard database management system (DBMS) for use in clinical trials management. The NCI is also using Oracle in developing its clinical trials DBMS standards. Our current CCS DBMS, Lotus Notes/Domino, uses a proprietary structure and search language. In contrast, Oracle is a standard relational DBMS and supports the internationally accepted database search language, SQL (Structured Query Language). For these reasons, we will evaluate the migration of the CCS and our other databases (described below) to Oracle.

Task 2: Database Development

Working with Ms. Elizabeth Bogan, a database consultant, we have assisted Drs. Debu Tripathy and Kiran Patel in developing both a clinical trials eligibility database and a patient follow-up database using the FileMaker Pro DBMS. The latter database now contains clinical information on over 700 patients seen in the BCC. Additionally, we have exported data from this database to text files, for preliminary studies by Dr. Jerry Miller of the CQI core.

Using the Access DBMS, we are also developing a BCC patient database using data elements common to breast cancer databases already existing at UCSF. Additionally, in collaboration with Dr. John Silva at the National Cancer Institute (NCI), we are trying to incorporate standard data elements and data structures into our database design. Ms. Gigi Medan, the Informatics Core project manager, has developed a matrix of all data elements common to the BCC database, the UCSF Breast Cancer Program Project Database, the UCSF Breast Cancer SPORE (Specialized Program of Research Excellence) Database, the UCSF Tumor Registry, and the NCI breast cancer database. We hope to contribute to the standardization of breast cancer data elements and data structures not only at UCSF, but also at the national level.

The databases mentioned above are currently being developed on microcomputers. As the scope of our project grows, we will consider porting them to a database server (UNIX or Windows NT) running Oracle.

Task 3: BCC Web Site

Mr. John Zhang, the newly hired Informatics Core programmer, has developed a publicly accessible Web site (http://bcc-ct.his.ucsf.edu) for the BCC, under the direction of Ms. Fern Hassin of the Education Core. This site contains information on breast cancer clinical trials at UCSF; an online newsletter regarding breast cancer research and treatment at UCSF; minutes from the Bay Area Breast Cancer Forum sponsored by the BCC; and links to other breast cancer sites.

We will continue to refine and expand this site during the next year of this project.

Task 4: Support for Other Cores and Projects: Machine-readable data

Along with the collaborative work described in detail above, we are providing support for other Cores and Projects. Dr. Jerry Miller of the CQI Core is developing statistical techniques to investigate patient outcomes. We have provided him with patient data from Dr. Tripathy's follow-up database to assist in his data analysis. We will continue to provide the CQI Core and other BABCP investigators with machine-readable data from our databases and from tumor registries to assist in their efforts to understand and analyze the data gathered as part of the BABCP.

We have met with members of the Psychosocial Core to assess their needs to automate their data gathering process. We have acquired the Teleform software package and a standard scanner to allow the development and implementation of machine-readable questionnaires. Unlike mark-sense forms and scanners, which are expensive and proprietary, this system allows the use of plain paper forms and inexpensive scanners. Using a Teleform-designed form based on a psychosocial questionnaire, our preliminary tests have shown 100% accuracy in scanning both filled-in "bubbles" and handwritten block letters. We will work with the Psychosocial Core and the BCC to develop this system during the third year of this project.

Similarly, as the Continuous Quality Improvement (CQI) finalizes the data elements it is collecting, we will provide them with machine-readable forms.

Other BCC functions for which we may provide Teleforms-based scannable forms, to be rolled out on a regular basis over the next year, include: same-day assessment; surgical trials and standards; patient follow-up; tumor board; and treatment summaries.

Task 5: Evaluation of Information Systems Technology

As described above, we are considering the choice of the Oracle relational DBMS as our standard platform, to which we could migrate both the CCS and the databases described above. We will pursue this issue further during the following year.

We are continuing our collaboration with Dr. John Silva at the NCI to develop standard data elements for breast cancer databases. As Dr. Silva described in a presentation to BABCP investigators, the database standards he is developing at the NCI include not only clinical trials information, but also all data elements necessary for "excellent patient care" of breast cancer and other oncology patients.

We have also met with Dr. Donald Simborg, the co-developer of the UCSF STOR (Summary Time-Oriented) system, which is a clinical data repository and partial electronic medical record (EMR) in use at UCSF. Dr. Simborg is the founder of KnowMed, a company that has developed a sophisticated EMR currently in use by the OnCare oncology group. Dr. Simborg demonstrated aspects of the KnowMed EMR to the BABCP group: His system appears to be more flexible and customizable than other systems we have seen. We will further evaluate Dr. Simborg's system, and its potential role in the BCC, in the upcoming year.

Staff Additions

We hired Mr. John Zhang for the Programmer/Analyst III position mentioned in last year's report. Mr. Zhang is responsible for the implementation of the projects described above.

Education Core

Education Core

The Education Core of the Bay Area Breast Care Program had a successful year. We set ambitious goals and with some exceptions were successful in meeting them. We implemented new programs and improved on existing ones in order to promote our dynamic and integrated breast care program.

We revised the Statements of Work for year two in order to give the most comprehensive and updated summary of our goals and objectives. This is based on our work from year one as well as experiences and feedback received during year two. We will continue to adapt these Statements of Work in order to provide the most beneficial education programs for patients, staff, and the community.

Year Two

1. In an effort to consolidate educational materials related to breast care, we have established an Education Core file cabinet, located in the Breast Care Center. This houses patient information, a professional literature bank, and information packets for newly diagnosed patients and those undergoing a biopsy procedure. This has already been a very useful addition, as it has increased access to both patient and professional information by all staff.

2. With the help of a patient, and members of the physical therapy, anesthesia, surgical and nursing staff, we completed informational packets for patients undergoing TRAM flap surgery.

3. We are committed to reviewing the latest materials with Breast Care Center staff so that they are aware of the available new patient education materials. We will conduct an inservice to review the contents of the new Education Core file cabinet with all the staff.

4. In addition to reviewing the educational materials related to breast cancer, we recognize the importance of staff educational sessions about the clinical aspects of breast cancer. A Breast Care Center physician led a four hour series for the staff to discuss this in detail. We plan to continue these in the next year as well.

5. One part of the Education Core file cabinet is a professional literature bank. This houses the most pertinent articles related to breast cancer. We complied this extensive group of articles with the help of the Breast Care Center physicians.

6. We worked in conjunction with the UCSF/ Mount Zion Cancer Resource Center and other Bay Area cancer organizations to establish a community wide resource database. This is the most comprehensive and up-to-date listing of resources for cancer patients. Because multiple organizations are working collaboratively on this project, we have been able to update the resources and ensure that we are providing information on the variety of services needed by cancer patients and family members.

7. We are continuing to offer individual introductory Internet classes to patients and staff as requested.

8. We outlined basic guidelines for using the Internet. We have distributed these guidelines to others including patients, the UCSF/Mount Zion Cancer Resource Center, and other Cancer Center practices to assist in the demand for instructional support.

9. We continue to increase resources and patient education materials in the UCSF/Mount Zion Cancer Resource Center. The Resource Center is used by patients, family members, staff and the community, so it is imperative to have a complete and updated library of resources. This includes books, videos tapes, audio tapes, and other materials.

10. As a way to highlight new resources, we sponsor a "Book of the Month" program in the Breast Care Center. Not only does it increase awareness of new breast cancer resources, but it also encourages people to utilize the Resource Center.

11. Another way we have highlighted new resources is through both the Resource Center and the Breast Care Center newsletters. These are regular publications that go out to the community and the staff respectively.

12. We are committed to community outreach and education. In year two, we have participated in many events to increase these efforts including, a major 7 week community wide art exhibit. The goal of the exhibit was to promote education and awareness about breast cancer. The Education Core was responsible for the coordination of the community resources for the event.

13. In addition to coordinating the resources, we also sponsored an evening event for UCSF patients and staff as well as the community at the art exhibit. The program, given by Breast Care Center physicians and the Director of Art for Recovery, focused on the relationship between art and healing. Again, the goal was to support the art exhibit and to increase awareness and education about breast cancer.

14. Other breast cancer community events we participated in were the "Race for the Cure" and multiple community and corporate health fairs. We provided educational materials and resources at these events.

15. We have standardized the resource materials we bring to community outreach events. The materials cover a wide range of topics and are in multiple languages as well. This standardization will help us evaluate the impact these materials have, rather than providing different materials at different events.

16. Finally, we need to document community outreach and evaluate the various types of outreach being offered. This documentation has been the weakest aspect of our community outreach efforts and will be a major focus of our efforts in year three.

17. We provided relevant articles or a reading list for each monthly Bay Area Breast Care Forum topic. These are monthly community education sessions which have been a very successful addition to our Breast Care Center's education and outreach.

18. In order to have an up-to-date literature bank, we receive weekly summaries of breast cancer related articles. We have built an online literature bank from these computer searches of most recent literature and coordinate the online bank with the other articles in the Education Core File Cabinet.

19. We initiated a monthly information session for women who are newly diagnosed with breast cancer. However, we found this was not successful because women do not wait for scheduled monthly session in order to get more information and support. This was not the best approach to meet the immediate needs these women have, so we have stopped the program. Other ideas for ways to meet this immediate need are being considered at this time.

20. We had the California State Guide Book translated into Russian, as we have a significant Russian speaking population in the Breast Care Center.

21. We are in the process of having the pre and post operative orders translated into Russian at this time. These will be complete by the start of year three.

22. We have gathered information about self breast exams and other patient education information in multiple languages.

23. We would like to standardize the post-operative orders for surgical staff and residents. This will eliminate any confusion in the directions we give our patients after surgical procedures. At this time, we are in the process of discussing these changes with the various providers. We expect to have made these changes shortly.

24. Along with the UCSF/Mount Zion Cancer Resource Center, we have developed a Cancer Center Discussion Forum. This is a monthly forum which brings in experts to discuss specific patient related issues. Past speakers have covered insurance and legal issues, and pain control. This month's speaker will address preparation for surgery both physically and emotionally.

25. We are in the process of developing a regular open house for patients based on successful model of community organization. The goal of the open house is to provide support to patients and family members and to help answer their questions. The open houses are run by a physician and then a professional facilitator. Depending on the specific numbers of physicians and facilitators who are willing to participate, we plan on offering these sessions every other week. We hope to start these sessions in the fall.

26. We have started a Patient Navigator Program in the Breast Care Center. Along with the Breast Care Center's Psychological Consultant and a Continuous Quality Improvement Analyst, we have recruited women who have completed their treatment at the Breast Care Center who are willing to work as Patient Navigators. Navigators will provide support and resources for women who are newly diagnosed with breast cancer. An additional component of this program is a division of patient phone contacts. These women will be phone resources for patients who want to talk to another woman who has faced breast cancer. The phone contact Navigators will have more short term contact with patients whereas the other navigators will provide more long term support.

Year Three

We are committed to continuing the programs that we have started in years one and two of the grant. In addition to maintaining these projects, we have set additional goals for year three.

Goals

1. To make sure we have coordinated packages of information to give patients undergoing their care at the Breast Care Center for:
    a. new diagnosis of breast cancer
    b. biopsy procedure
    c. surgery for cancer
    d. chemotherapy
    e. radiation therapy

These packages will be in folders with the appropriate contacts.

2. To work with Continuous Quality Improvement team to identify and implement clinical changes including those related to patient and provider education.

3. To build patient information packets about chemotherapy.

4. To build patient information packets about radiation therapy.

5. To make an abbreviated list of the most pertinent articles from the literature bank for use by new surgical and medical residents, medical students, staff, and highly sophisticated patients.

6. To translate the California State Guide booklet and the pre/post operative surgical orders into Chinese.

7. To assist with the coordination of the educational materials for clinical trials.

8. To write and review an information sheet on the new sentinel node biopsy procedure.

9. To improve on tracking and evaluation of new and existing programs

10. To coordinate the inpatient and outpatient services related to breast cancer and to conduct inservices of nurses about programs, methods, post operative instructions and care related issues

Our primary goal for year three focuses on the improvement of the evaluation, documentation, and analysis of our educational programs. We have implemented many successful programs, yet we feel that we are not tracking the effectiveness of these interventions in the most effective manner possible. We will examine each program and determine ways to improve our data collection and evaluation methods. This will help us conduct even stronger outcomes research.

Project 1

Project 1

Evaluating Cost Effectiveness in the Diagnosis of Breast Abnormalities

Introduction

Breast cancer remains one of the leading causes of mortality and reduced quality of life for women in the United States. Although controversies persist as to when mammography screening is most beneficial, mammography remains the cornerstone of programs to improve the early detection and diagnosis of breast cancer. Relatively little is known about patterns of care once a woman receives a report of an abnormal mammogram. Currently, there are a wide variety of management options for further evaluation of abnormal mammograms, and this evaluation is typically orchestrated by the womanís primary care provider. Unfortunately, there are no widely accepted guidelines for the management of women with a breast screening abnormality. Techniques for further evaluation may include technology that differs in invasiveness, diagnostic certainty, timelines of resolution and patient anxiety and satisfaction. Since most of these women are not ultimately be given a diagnosis of cancer, it is particularly important to consider the role of further evaluation on patient satisfaction and anxiety since this may influence patient adherence with recommendations for subsequent screening. The continuos quality improvement (CQI) component of this project has been responsible for the ongoing development and testing of specific evaluation protocols. The purpose of this research component is to evaluate differences in the evaluation of women with an abnormal mammogram and to see whether differences in evaluation are associated with differences in patient satisfaction.

Aim 1

This Aim has been significantly modified due to the merger of CPMC and UCSF Medical Groups, as described in last years Annual Report. Patients from these sites can now cross-sites and for this reason a comparison based on a comparison of the sites is no longer valid. Instead, we are sampling women from both sites, but the analysis will focus on differences in management by the primary care provider after the report of an abnormal mammogram. We will look at factors associated with differences in evaluation, timelines of resolution of the abnormal finding, patient satisfaction with their evaluation and the effect of evaluation on adherence with subsequent screening.

The new study protocol is summarized below with an updated progress report.

Hypothesis:

Patients who report more coordinated care for an abnormal mammogram will have higher satisfaction with care, more timely resolution of their breast problem, fewer diagnostic tests leading to a resolution, and less anxiety about future mammography.

Objectives:

For women with an abnormal mammogram, determine whether more coordinated care is associated with lower variation in the number and type of evaluative tests, more timely initiation of evaluation, fewer diagnostic tests, and shorter time to diagnosis of breast abnormalities compared to less coordinated care.

Determine factors associated with differences in satisfaction with care among women being evaluated for abnormal mammograms.

Determine whether the costs of care for women with more coordinated care are lower than the costs for women with poorer coordination of care.

Methods:

Women who receive a report of an abnormal mammogram from the University of California, San Francisco (UCSF) or California Pacific Medical Center (CPMC) will be eligible to participate in this study. Women will be identified using the radiology information systems at CPMC and UCSF. Both sites participate in the San Francisco Mammography Registry, and therefore generate standardized mammography reports based on the American College of Radiology Breast Imaging and Reporting Data System. Women will be eligible to participate if they: (1) are 40 ñ 79 years old, (2) have no prior history of breast cancer , (3) have not received a report of an abnormal mammogram within the preceding year, (4) are English- or Spanish-speaking, and (5) receive a report of a BIRAD Class 3 (abnormal, probably benign), 4 (suspicious abnormality, consider biopsy), or 5 (highly suggestive of malignancy) during the study period at one of the participating sites. Women who agree to participate will be contacted by phone 4 - 8 weeks after their index mammogram to complete a survey asking about demographic characteristics, prior episodes of breast problems, coordination of care and satisfaction with care. Women will be reconnected by phone again approximately 8 months after their index mammogram to ask about adherence to recommendations for further evaluation, patient-reported quality of care and satisfaction with care. Clinical information systems at CPMC and UCSF will be used to obtain information about the use of further radiographic testing and any cytology or pathology testing. Recruitment will continue until 300 women are recruited from each site. We plan to have the sample stratified so that there are 150 women with a Class 3 abnormality (abnormal, probably benign) from each site and 150 with a Class 4 or 5 abnormality (more suggestive of malignancy).

Task 1:
Recruitment began for this project in June, 1998. CPMC performs approximately 25,000 mammograms per year. We expect that approximately 4% of these will be Class 3, and 2% will be Class 4 or 5. We expect that 80% of women will agree to participate. It should therefore take less than five months to recruit the patient panel at this site. UCSF performs approximately 15,000 mammograms per year. We expect that 7% of these will be Class 3 and 4% Class 4 or 5. Again, we expect and 80% participation rate. We therefore anticipate that we should recruit our study sample within five months.

Task 2:
Two surveys telephone survey instruments have been developed for this project (appendix N). A baseline survey is completed within four to eight weeks of the index mammogram and a follow-up survey is completed eight months after the index mammogram. Both of these instruments have been translated into Spanish.

The baseline survey asks about sociodemographic characteristics, health status, duration of relationship with primary care provider, site of primary care, anxiety about breast cancer, recent breast symptoms and duration, coordination of care related to index mammogram, access to breast care, satisfaction with care, lost work, and intention to adhere to follow-up recommendations. The follow-up survey asks about adherence to follow-up recommendations, type and timing of further evaluation, barriers to follow-up, anxiety about breast cancer, coordination of care, satisfaction with care and out-of-pocket health care costs related to the index mammogram. The surveys are being administered by a professional survey company using computer assisted data entry (CADE), to ensure high quality data.

Task 3 / Task 4:
A computer database has been developed to collect standard medical record information for each participating patient. This database is stored on a laptop computer and will be used by a research assistant to record standard information about diagnostic evaluation of the index mammogram and the results. Breast pathology records from UCSF and CPMC will be reviewed for all study participants. Dates of procedure, type of procedure performed and cytologic or pathologic findings

will be recorded. Mammography records will also be reviewed to capture any further radiographic testing. The clinical information systems of UCSF and CPMC will be reviewed to obtain information about insurance status, provider visits and utilization. Medical record information will be abstracted for each patient at the time of the administration of the follow-up survey.

Task 5:
Data Analysis:
Patient-reported coordination of care will be used to stratify women into groups with more or less coordination. Critical diagnostic paths will be described for each class of breast abnormality (Class 3, Classes 4 and 5). Descriptive statistics will be used to compare variations in the use of diagnostic tests between the women with different degrees of coordination.
Outcome variables to be examined include: time to first test, time from abnormal mammogram to diagnosis/disposition, number and type of diagnostic tests, use of surgical biopsy following fine needle aspiration, and cancer/biopsy ratios. Special attention will be paid to the time from abnormal mammogram to first diagnostic test and if a cancer is diagnosed, time to excision. Overall scales of patient satisfaction, examining different aspects of care will be compared, including satisfaction with staff, communication with provider(s), understanding of tests, and levels of anxiety/quality of life. Women will also be specifically asked about loss of productivity and time lost from work related to their evaluations for breast abnormalities. Cost comparisons will be conducted to compare women who report more versus less coordinated care. Average charges will be estimated by collecting general charge information for each type of diagnostic test from both participating hospitals, and estimating a mean charge. Standard cost-to-charge ratios will be used to translate hospital charges into costs. These data will then be combined with data on the patterns of evaluation collected as part of Objective 1.

Descriptive data on the types of diagnostic tests will be stratified, based on class of abnormality, patient age (less than 50, or age 50 or more) and family history. Rates will be compared using a chi-square statistic. Preliminary data has shown that the outcome variables of time to diagnosis/disposition and number of tests are not normally distributed, so non-parametric comparison of medians will be performed. Descriptive data on satisfaction with care will be stratified, based on class of abnormality, patient age (less than 50, or age 50 or more) and family history. We will look at the association between sociodemographic characteristics, patient-reported coordination of care and satisfaction with care. Stratified by class of mammographic abnormality, costs per cancer detected will be calculated and compared. Differences in cost estimates will therefore be primarily driven by higher rates of more expensive diagnostic tests per cancer detected. Since the analysis will be based on average charges, the emphasis will be placed on the comparison, rather than on the total charges themselves.

Sample Size:
We will recruit a total of 600 women, 300 with probably benign abnormalities and 300 with more concerning abnormalities. We expect that the proportion of women in the better coordination group will be between 20% and 50%. This sample will give us a power of over 90% to detect a difference of 4 days in the timelines of evaluation for women with better/ worse coordination of care (alpha=0.05, two-sided test). The proposed sample will give us a power of over 90% to detect a difference in the rate of excellent care of 16% across a wide range of satisfaction rates.

Aim 2

Task 6: Questionnaire Development (See above).

Task 7: Data analysis
1043 consecutive fine needle aspiration biopsies (FNAB) of palpable breast masses were reviewed. Of these, 729 specimens were collected by formally trained operators in a breast clinic

setting. All of these trained operators perform at least 100 aspirations/year. The remaining 314 specimens were collected by operators who lacked significant training in the FNA procedure. Most perform less than 10 FNABs/year. The busiest operator in this group had performed 43 FNABs in the year investigated.

All reports and slides were pulled. All slides were reviewed without knowledge of the original interpretation. Degree of epithelial cellularity and presence of non-epithelial components were recorded. Based on the material present on the slides and the clinical data available on the cytology request form, a judgment was made as to whether or not the material was diagnostic. For example, if a definitely or moderately firm mass was described, but only scant epithelial cells and fragments of adipose tissue were seen on the slides, then the specimen was deemed non-diagnostic because the cytologic findings were inconsistent (did not explain) the clinical finding. On the other hand, if similar cytologic material was seen in the setting of an ill-defined soft thickening of the breast, which was deemed to have little potential for being clinically malignant, then the cytologic material was consistent with the clinical findings and was considered diagnostic in this study. Upon review of the slides, an independent cytologic diagnosis was rendered in all cases when available. In addition, all cases without surgical follow-up and all but 77 of the cases with surgical follow-up were submitted to Survey End Epidemiology Result (SEER), a population-based cancer registry that covers all seven counties of the greater San Francisco Bay area. The FNAB cases were matched with subsequent breast cancer diagnoses in the cancer registry. A minimum of two years follow-up was available in all cases.

In cases in which the patient was diagnosed with cancer initially or during the two-year follow-up, the fact sheet from the cancer registry, the pathology report, and/or the patient's chart was reviewed. The location of the FNAB was matched with the location of the cancer in the breast. Furthermore, the size of the tumors were recorded, as was tumor type.

Results:
The trained operators had a sensitivity of 98% for detection of breast cancer, as compared to 75% for the untrained operators. The entire difference between the accuracy of the 2 groups was due to sampling error. Only one failure to recognize cancer under the microscope was found between both groups of cases. The amount of material collected by the trained operators was much larger on the average, which most likely impacted positively on the accuracy of the test. Thus we found that the level of training in the FNAB procedure had great impact on the reliability of the test.

There were significant reductions in morbidity and cost when FNAB was applied by the trained operators compared to the untrained ones. This is due to the fact that only 8% of benign lesions were surgically excised after FNAB by trained operators, as compared to the 30% benign excision rate that occurred when untrained operators had performed the FNABs. The UCSF FNAB service providing FNAB for the UCSF-Mt. Zion Breast Care Center employs only physicians specifically trained in the FNAB procedure. Most of the physicians outside the UCSF FNAB service are not trained in the procedure.

A manuscript detailing these results is currently in preparation.

Aims 3 & 4
The patient satisfaction and the cost components of this project has been integrated into Aim 1 because of the merger of UCSF and CPMC. Data collection for these Aims was initiated in June, 1998.

Conclusion

This project, which needed significant re-design because of the merger of UCSF and CPMC, has now completed revision of the study design and finalization of all of the study instruments. Data collection has been initiated and is expected to continue throughout the next project year. We believe that this project will yield important information about variation in the management of women with an abnormal mammogram, and the effect of this variation on patient satisfaction and subsequent adherence with screening recommendations.

Project 2

PROJECT 2

Psychosocial Program

This program is a randomized clinical trial comparing the effectiveness of two pyschosocial interventions, a standard support group versus and integrated program incorporating complementary techniques such as yoga, meditation, imagery and dance along with a psycho-spiritual support group. Participants will be randomly assigned to the groups, and measures will be gathered at baseline, three months, six months, and one year following study entry.

The overall purpose of this project is to compare an individualized vs. an integrated/intensive support program for women with breast cancer. in year 1 we set up the structure for the project and began to address the goals for the project. Year 2 continued the work on the goals for the project, which are to directly compare the two approaches (i.e., changes in psychological distress coping, quality of life, etc.), explore which women do better with which type of intervention, and examine long term outcomes such as time to progression, survival, costs, quality of life, etc.

The original statement of work for this program is delineated by the tasks below:

Task 1: Set up clinic for research, Months 1-3:
a. Hire secretary and social worker.
b. Purchase computer, printer, phones.
c. Ensure availability of group leaders.
d. Prepare assessment packets for patients to complete.
e. Ensure that physicians are aware of the psychosocial program.
f. Write information package describing the program and the interventions available.
g. Set up procedure for inputting data into database-coordinate with Informatics Core.

All of the objectives in Task 1 have been achieved. However, we have inputted the data into our own database, and are working with the Informatics Core to set up a database that is accessible to other projects in the program.

Task 2: Initial assessment and treatment of patients, Months 4-16:
a. Begin patient entry into research program. Assessment of women as they enter program.
b. Piloting of data collection mechanisms
c. Piloting of intervention groups.
d. Conduct follow-up assessments as the interventions are completed.

Task 2 has been completed. Analyses on the pilot data have been conducted, and a preliminary report is attached.

Task 3: Aim 1: One-year follow-up, Months 17-18
a. Collect one-year medical data from data base in order to complete Aim 1.
b. Collect one-year follow up for all women in the program (assess psychological status, coping style and quality of life) in order to complete Aim 1.
c. Determine number of women who participated in the interventions.
d. Perform analyses of data collected to address Aim 1.

We are almost at the point where we can begin to collect one-year follow-up data from the women in the pilot cohort. We will collect that data in the fall of 1998.

Task 4: Testing Aims 2-3, Months 17-44

a. Add wait-list control groups. Begin to randomly assign women to immediate or wait-list groups.
b. Continue baseline and post-intervention assessments.
c. Continue yearly assessment of all women entered in the program.

We have had a wait list group out of necessity, rather than by randomization. Many women have not been able to join the next cohort, because of time restrictions (e.g., the next cohort runs in the afternoon, and they can only come in the evening), medical issues (e.g., a woman was waiting to have a stem cell transplant done), and no more room in that particular cohort. We are continuing to gather post intervention from the women, and for the women who are on the wait list, we gather information at the beginning of their waiting period, and again when the group starts (as well as follow-up data after the group ends).

Other accomplishments not on SOW:

1. Team building exercises have been conducted and are ongoing.

2. We have been approved as a practicum site for graduate level students from the California School of Professional Psychology-Alameda. These students assist with the research (interviewing of women, collecting data, co-leading groups, etc.). Two of the three the graduate students we currently have presented aspects of this research at the annual meeting of the American Psychological Association in August 1998. A third graduate student has conducted her dissertation based on data obtained in the project. This dissertation examined the role of coping strategies and post-traumatic stress symptoms among women with breast cancer and will be submitted for publication. Two more graduate students will begin in the fall to assist in research and clinical activities.

3. We have been approved as a practicum site for Social Work interns through the Mount Zion Medical Center. One social work student has begun training in the Integrated program.

4. We have been approved as a clinical rotation site for Psychiatry residents at both UCSF and CPMC. A fourth year psychiatry resident participated with the program over the last 12 months, and has now been hired by the program as part-time staff leading groups and doing individual psychotherapy and medication evaluations. A second UCSF fourth year resident will be beginning in the program next week.

5. Training seminars are being devised for the above students/interns, and will begin in the fall of 1998.

In order to recruit more program participants, we have opened up enrollment to woman who meet the study criteria from institutions other that CPMC and UCSF. This was done in response to some difficulty in recruiting enough women from the sponsoring institutions. We will still be able to get all necessary medical chart data from these women and will participate with their medical teams in the same way as we do with patients from UCSF and CPMC. An important result of this change is we now have a much broader mix of ethnicities and socioeconomic status.

In summary, we have spent the second year implementing an entirely new and different program for women with breast cancer for comparison with a group representing the community standard. Data collection is now underway, and the preliminary analysis from the pilot cohort are attached. The women who have entered our program so far have been pleased with the center, the program, and the group that they have been randomized to. Although the pilot sample was small, the initial data also shows that both of the interventions resulted in significant improvements in positive mood and quality of life. Despite the rigor and time intensity of the Integrated program, both of the interventions have been shown to be feasible, both for the staff and for the patients.

Plans for Year 3 include:

1. Continuation of recruitment and running of groups, including efforts to attract more minority women;
2. Analysis of the first 100 women who have gone through the program (Aim 1);
3. Depending upon the results of the analyses eliminating the randomization aspect of the research and begin to study the choices that women make for complementary treatment (Aim 2);
4. Presenting data at various scientific meetings (e.g., Society of Behavioral Medicine)
5. Submission of papers to referred journals;
6. Continue to collect follow-up data;
7. Continue to train students/interns/residents.

Project 3

PROJECT 3

Introduction

The goal of this project is to try to accurately assess a patient's risk of recurrence and death due to their breast cancer by finding common ways to represent risk of recurrence to patients which incorporates the latest established evidence; and then to test patients' perception of risk and how it influences their choices when the representation is made in terms of time and probability of recurrence. Additionally, we will assess the expected benefit of adjuvant therapy.

A significant roadblock was identified as the lack of calibration of risks of mortality and recurrence prior to adjuvant therapy. In addition, agreement was required on the interpretation of several key large new studies, as well as the 1995 world overview analysis. These studies revealed significant new estimates of benefit from adjuvant therapy. We successfully completed our first "Calibration Conference" and will be using the information in software to test patient preferences for adjuvant therapy, starting this fall.

Technical Objectives 1-2

We have obtained recurrence and mortality estimates for early stage breast cancer patients using both SEER and San Antonio Tumor Bank databases. We have also developed graphical and written tools for the Shared Decision Program. [COMPLETED]

Task 1

Dr. Peter Ravdin obtained mortality and recurrence estimates and revised his model and displays. Further input was provided via a focus group with patients and advocates who evaluated the computer model and the graphs it generated. Dr. Ravdin incorporated the focus group suggestions into his computer model and display sheets. [COMPLETED]

Task 2

The hypothetical risk questionnaires were piloted during the focus group. We modified the risk text and figures for clarity. The revision of the text and graphics depicting delay versus prevention of recurrence and death was accomplished through meetings with Drs. Laura Esserman, Debu Tripathy, Peter Ravdin and Al Mulley. Dr. Mulley has decided to revise the shared decision making program from a videodisk format to a CD-ROM format, as well as modifying the presentation of the information accompanying it which is given to participants. Drs. Esserman and Tripathy participated in the review and revision of the presentation information. The hypothetical questionnaire, risk questionnaire and pre- and post-viewing questionnaires have been evaluated by patients and advocates, refined, and are currently being submitted to the Institutional Review Board.

Task 3

To track eligible patients, we are using the Filemaker Pro database, designed for Pilot A, to identify early stage patients eligible for Project 3. Due to the delays we have encountered because of the change in the format of the Shared Decision Making Platform, we are looking at ways to speed up patient enrollment so that our time estimates can stay on target. We feel that this can be accomplished by contacting physicians and nurse practitioners at California Pacific Medical Center, SFGH, and Marin General Hospital to help identify patients for Project 3. The change to a CD-ROM format will make the program more portable, and therefore should enhance our ability to meet our goals. Drs. Esserman and Tripathy were able to participate in the review and revision of the text material and, along with input from our patient advocates derived from our focus groups, have been able to improve the quality and informational value of the testimonials which will appear in the revised CD-ROM. We will also explore the possibility of an Internet version whereby we

will obtain consent, all demographic, clinical and questionnaire input, and display the same output information over the Internet (similar to the mammography questionnaire done by Kerlikowske and Ernster for the UCSF Breast SPORE). In order to achieve a consensus on baseline estimates of risk, relative risk reduction, the values used for these estimates, and the method used to display these estimates on the CD-ROM, we hosted a full day Calibration Conference attended by statisticians, hematology oncology physicians, advocates, and webpage designers. The agenda included the preliminary exploration of additional adjuvant therapies (biphosphonates and radiation) and their effect on overall risk reduction, as well as strategies for using the Internet to survey large numbers of patients quickly. We have adapted and clarified the goals of Project 3 to better accommodate patients' decision making needs by revising the existing shared decision making video disk program. The availability of CD-ROM technology with it's flexibility and portability will allow us to modify the original program and still allow enrollment of an adequate number of patients.

We were interested in testing patients' understanding of time gained versus risk of recurrence. After much discussion about how to test these concepts, we have decided to randomize patients to two arms. Arm 1 will receive graphs informing them about their risks of recurring and dying with and without therapy. Arm 2 will receive the same graphical information in addition to information about the average amount of time a patient gains if she uses adjuvant therapy.

Finally, our goal for year 3 is to calibrate the data on recurrence and death, place it into an appropriate educational vehicle (CD-ROM) and begin to recruit patients, first in the clinic, and ultimately to develop a design to incorporate the Arm 1 and 2 trial on a website. One of our first Fall Bay Area Breast Cancer Forums (a project of Pilot A which features interesting topics on breast cancer and clinical trials for advocates, patients, families, and community members) will be entitled: "Calibrating Risks and Benefits in Early Stage Breast Cancer: The Role of Shared Decision Making". The goal of the evening will be to develop interest in the community for the trial and the website.

Project 4

Project 4

Decision-Coordination for Patient-Physician Consultations at the UCSF Breast Care Center

Introduction

Changes in Statement of Work since the last annual report:

Jeff Belkora assumed co-leadership of Project 4 upon finishing his Ph.D. at Stanford. Along with Project IV staff Stephanie Lamping and Karen Cushing, Mr. Belkora had completed a clinical trial in Year 1 of Project IV that substantially exceeded expectations for power (Beta = 0.8), significance ($p<0.05$), and sample size ($n=119$). The Stanford Center on Conflict and Negotiation awarded its 1997 Goldsmith Prize for Best Paper on Dispute Resolution to Dr. Belkora's clinical trial report. (Belkora JK. Impact of Consultation Planning on Collaborative Decision-Making in Medicine. *Stanford University Center on Conflict and Negotiation.* 1997.) A similar paper is now being submitted to a leading medical journal.

For Year 2 of Project 4, Dr. Belkora reoriented the team so that it is focused on piloting new applications of Consultation Planning, rather than conducting further clinical trials as was originally foreseen. Thus the team's focus on second opinions, the training program, and on DCIS controversies were not present in the annual report for Year 1.

Tasks 1 (Consultation Planning for Second Opinions) and 2 (A Training Program in Consultation Planning) proved to be straightforward extensions of Year 1, and were duly completed on time and on budget. With Task 3 (Ductal Carcinoma in Situ, DCIS), we clarified the limits of Consultation Planning in the absence of data on disease progression in breast cancer. In terms of the Statement of Work promised, Project IV completed Tasks 1 and 2.

The Project IV staff also focused on tasks not foreseen in the Year 2 Statement of Work. Most notably, we coordinated our activities with members of the Continuous Quality Improvement (CQI) Core. Together, we have forged a common vision for decision support in the BCC, a vision that we call Collaborative Care Facilitation (CCF).

CCF will consist of three sequential interventions: Consultation Planning (visit preparation); Consultation Recording (visit facilitation); and Collaborative Treatment Selection (evidence and preference-based medicine). Our joint goal with the CQI Core is to have a trained cadre of Collaborative Care Facilitators by the end of Year 4, along with validated metrics to assess the quality of our services. CCF will then be embedded in the Breast Care Center's operations, including its multidisciplinary Tumor Board.

Year 2 of Project IV therefore included planning and design activities for the coordinated roll-out of these services by the end of Year 4. We also completed the design of metrics to assess the effectiveness of Collaborative Care Facilitation.

In Year 3 we expect to continue expanding the Consultation Planning and Consultation Recording interventions so that they may be offered to all BCC patients. We also will continue developing our training program so that it may underwrite the expansion of Consultation Planning and Recording. Meanwhile, our existing Consultation Planners will learn the elements of Collaborative Treatment Selection from Jerry Miller, Carrie Sanders, and Meridithe Mendelsohn of the CQI Core. The Consultation Planners, CQI staff, and Resource Center staff will form the first cadre of BCC facilitators.

By the end of Year 3, we should be able to offer the full scope of Collaborative Care Facilitation services to a limited number of BCC patients in a pilot program. In Year 4 we will train additional BCC facilitators and expand CCF offerings to all BCC patients.

Report on Year 2: Work Completed within Original Scope

Task 1: Consultation Planning for Second Opinions

The need for Consultation Planning before second opinions was highlighted during our scoping phase, when we noticed that physicians at the Tumor Board would often express confusion as to "what exactly does the patient expect from us?" The printed Consultation Plan that results from our intervention summarizes what questions and concerns a patient needs the doctor or Tumor Board to address during a second opinion consultation.

Subtask 1: Consultation Planning for Second Opinions

As of January 1998, Consultation Planning (CP) is listed as an option on the tumor board requisition form. If physicians indicate that a patient desires CP, we schedule a session with that patient. We have been put on the scheduling system so that the front desk staff and others can schedule CP sessions for us.

As of January 1998, Consultation Plans are printed out and attached to the tumor board outline. During case presentation, a Consultation Planner summarizes the main questions and concerns as displayed in the printout. Physicians and others frequently refer to the Consultation Plans during case discussion.

As of October 1997, we have expanded the scope to include new patients consulting with surgeons and oncologists about options for treatment, in addition to second opinions at the tumor board. Since October 1997, two Project IV staff members (Karen and Stephanie) have worked with 34 patients, 14 of whom were scheduled for tumor board. These patients were scheduled to consult with a range of specialists: 1 surgeon, 1 plastic surgeon, 4 oncologists and 2 radiation oncologists. Further, we have two trainees (Kristie Dold and Carrie Sanders) who have sat in on 6 CP sessions and Kristie has already conducted one CP session herself.

Subtask 2: Understand the issues surrounding decision making from the physician's perspective

Through March 1998, we focused on the multidisciplinary tumor board that convenes for second opinions.

Between September 1997 and March 1998, we tape recorded 15 tumor board sessions and transcribed two which document different communication dynamics.

The Tumor Board environment proved to be too complex—too many participants interacting simultaneously—to diagnose barriers to effective decision-making among physicians.

Therefore, beginning in March 1998, we have begun focusing on individual patient-physician consultations. We have sat in on and audiotaped 20 consultations where patients and physicians are discussing how to treat breast cancer.

Subtask 3: Extend Consultation Planning techniques to capture discussion at tumor board and generate a Consultation Record of the proceedings

In January 1998, we adopted the practice of recording tumor board case discussions at a printing white board. A copy of the notes are printed for BCC records and for the presenting physician when the discussion is complete.

Subtask 4: Facilitation of patient-physician consultations

In February 1998 we initiated a pilot study to explore the impacts of creating a Consultation Record during high-stakes patient-physician consultations. The idea is to relieve patients and physicians of the burdens of note-taking and agenda management by having a trained facilitator annotate the patient's Consultation Plan during the consultation. The facilitator thereby creates a Consultation Record, summarizing the physician's responses to patient questions and concerns.

Since February 1998, 8 patients have been recruited into a pilot experiment evaluating the impact of Consultation Planning and Recording on breast cancer consultations. We anticipate enrolling 20 patients into balanced control and intervention groups by September 1998.

Subtask 5: Coordinate with other BCC Cores the assessment and comparison of health and cost outcomes of these interventions.

We have identified standard metrics for anxiety and depression that we are considering implementing in our future pilot trials of Collaborative Care Facilitation.

In conjunction with the evidence-based medicine arm of the CQI Core, we have created Likert Scales to assess when patient levels of decision-readiness, and patient and physician satisfaction with consultations. We have also tested the reliability of the CBHP Scale of Communication Barriers (Cronbach alpha = 0.75) and the Satisfaction with Interview Scale (Cronbach alpha = 0.71). These Likert Scales are reprinted in appendix O.

Task 2. Training Program for Consultation Planners

The purpose of Task 2 was twofold. First, we wanted to provide an ongoing forum for learning and reflection among Consultation Planners. Second, we planned to develop an introductory curriculum for Consultation Planning.

Consultation Planning Forum:
This group convened itself weekly between October 1997 and July 1998 to reflect on Consultation Planning experiences. The core members are Jeff Belkora, Karen Cushing, and Stephanie Lamping. Occasional participants include Jerry Miller, Carrie Sanders, and Meridithe Mendelsohn of the CQI Core, and Kristie Dold and Keren Stronach of the Cancer Center Resource Center. The Forum has honed its skills in all the phases of Consultation Planning. We have applied SPIN Selling techniques to Contracting; Action Science methods to Surveying; Decision Analysis tools to Mapping; and established counseling methods to Debriefing. We are now investigating how Neurolinguistic Programming to may help Consultation Planners establish rapport with clients.

Training Curriculum:
Between September 1997 and February 1998, we convened six meetings of the Bay Area Consultation Planning Affiliates Conference. This focus group included nurses and other health care providers from Marin General Hospital, Kaiser Oakland, Alta Bates Medical Center, the Palo Alto Medical Center, and the Stanford University Health Improvement Program. Our purpose was to pilot our training curriculum with a group of experienced practitioners who could provide critical feedback.

We exposed this group to videos, books, and transcripts, as well as role-plays and commentaries. We tracked our training program's effectiveness through pre/post administrations of a new Likert

Scale, the Consultation Planner Training Survey. The feedback we received was that our videos and texts were of limited usefulness compared to the coaching and role-plays. Specifically, the videos need to be edited so that they are shorter and free of extraneous material like interruptions and delays. Likewise, the texts (How to Make Meetings Work, The Skilled Facilitator) need to be excerpted into a concise handbook or guideline.

BACPAC participants applauded our structured role-plays. Role-players selected from a library of past Consultation Planning cases to prepare their part and then acted it out while one of their peers recreated the Consultation Plan. The divergence between the original and recreated Consultation Plans stimulated high quality reflection and discussion after each role-play. Our next task is to create a training binder to accompany the library of past cases so that future trainees may progress rapidly through didactic instruction and on to practice.

Task 3. Decision Modeling for DCIS

In order to help DCIS patients evaluate a watchful waiting treatment alternative, they must be informed of the likelihood of progression to invasive cancer during the waiting period. Initially we intended to use current DCIS data to estimate the progression rates of DCIS via simulation. After contacting several data sources and meeting with a variety of physicians (through December 1997), it became apparent that DCIS information is not currently collected in a way that is useful for this problem. Because clinical practice is to remove DCIS lesions as they are detected, data that tracks the disease over time is non existent. Therefore, our preliminary model formulations are purely speculative.

Therefore, since January 1998, we have been honing our decision modeling skills in the area of genetic testing. As in the DCIS arena, patients and physician considering genetic testing are dealing with a known increased potential for life threatening disease rather than the disease itself. Unlike the DCIS arena the information necessary to evaluate the feasibility of genetic testing programs is becoming increasingly available. We have created a model that is used to evaluate various genetic testing and prophylactic care programs. Our metrics are number of life years saved and cost of implementation and care.

From this work we have surfaced the need for more specific methods of determining a patient's a priori risk of carrying a BRCA1 or BRCA2 mutation. With this information we will be better able to identify a testing population that will benefit from the program. As a result we are collaborating with researchers at Duke University to determine the impact of new risk prediction methodologies on genetic testing program cost.

Our experience developing the genetic model has helped us reframe the DCIS decision modeling dilemma. Rather than trying to modify existing questionable data in order to build a model, we recommend the adoption of a reverse engineering approach. Researchers should work with physicians and patients to surface their concerns about a watch and wait treatment strategy toward DCIS. Having uncovered the issues that are crucial to acceptability of noninvasive treatments, researchers can determine the cost of gathering information that would mitigate those concerns. If the costs are acceptable, simulation methods can produce a plan of action for information gathering. Because these methods will direct efforts towards collecting information that is a priori pertinent to patients and physician facing DCIS treatment decision, the resulting models will have an increased chance of being used clinically.

Summary of Results, Implications, and Conclusions

The creation of a joint plan with the CQI Core for decision support in the BCC proved to be the most significant event of Year 2 for Project 4. This new vision for decision support, which we call Collaborative Care Facilitation, sequences two Project 4 interventions—Consultation Planning and Recording—with a third, CQI intervention, namely Collaborative Treatment Selection. By the end of Year 4, BCC patients entering the BCC will be offered visit preparation, visit facilitation, and the evidence-based analysis of treatment options. Many researchers have tackled pieces of this puzzle, but the BCC will be the first clinic to integrate them.

Other Project 4 achievements in Year 2 include the creation or validation of a full suite of Likert Scales to assess the effectiveness of Collaborative Care Facilitation. In addition, we also created a survey for assessing the impact of our training program (see appendix O).

Our goal for Year 3 is to develop the next phase of collaborative care, consultation recording, and the creation and recording of the treatment and decision plan, with a written summary for the patient.

Pilot Project A

PILOT A

Introduction

The following is a detailed description of the goals we have met and a comprehensive description of future plans. The goal of Pilot A is to develop a model to assess need, and develop focused tools to improve the number of patients and patient diversity in clinical trials for breast cancer. Of note, the tracking system developed for Pilot A has proven to be an extremely valuable tool for other aspects of patients care in the Breast Care Center. This tracking system will be modified as a more comprehensive informatics system is implemented in the Breast Care Center.

Technical Objectives 1-2:

Task 1
Data forms and appropriate fields for the collection of patient information have been developed. These were submitted to physicians for their review and comments. The finalized forms are incorporated in a Filemaker Pro database which contains six tables that capture detailed information about patients' demographics, medical histories, clinical and pathological variables, therapeutic and recurrence data. [COMPLETE]

Task 2
Physicians complete these forms (appendix P) on all patients who visit the Breast Care Center. The completed information is then entered into the Filemaker Pro database. Additional information not initially captured has been entered by a data manager. We have now been collecting this information since June, 1997, and currently are receiving data on 100% of medical oncology patients, and approximately 80% of surgical patients. (See Data Analysis, appendix R). This data will be additionally useful to track patients eligible for open clinical trials, as well as to evaluate the patient population to develop protocols for new clinical trials. Current calculations (6/4/98) based on 9 months of data show that 7% of patients eligible for trials at the BCC are enrolling on treatment trials (this number will be higher when we include imaging (MRI) trials and this is now being gathered).

Task 3
130 Bay Area oncologists, surgeons, radiologists, etc. were identified to receive the survey which assesses caregivers' opinions about the obstacles to clinical trial enrollment. [COMPLETE]

TASK 4
We have received, tabulated the results and reviewed the open ended questions of 70 surveys. [COMPLETE]

Task 5
We have used our Filemaker Pro database to identify patients who were eligible to receive our survey about patients' opinions about barriers to clinical trials. After patient advocates and patients reviewed our pilot questionnaire, we revised the survey and resubmitted it to the Institutional Review Board. We have administered, received and tabulated the results of 150 patient questionnaires. The resulting data was submitted to ASCO and was published as Abstract #686: "Physician and Patient Barriers to Enrollment on Breast Cancer Clinical Trials", in the Proceedings of ASCO, Volume 17, 1998 (appendix Q). In addition, we have used our database to link the patients who have taken the survey to their demographic and medical information. Final analysis with respect to these other clinical variables will be completed shortly. A separate questionnaire is being developed regarding patients' attitudes and

understanding of tissue research. Although this was not an original aim of the grant, it has surfaced as an important area of interest.

Year 2 Tasks

Although Tasks 6-8 were expected to be initiated during Year 2 of the grant, all three were actually begun in Year 1.

Task 6
A flow chart has been developed which lists all the clinical trials available at the Breast Care Center according to their eligibility requirements. This chart is updated monthly and is available to all physicians in the clinic and at weekly tumor board meetings. Additionally the chart is posted on the UCSF Cancer Center website with links to the Breast Care Center Clinical Trials website. During the second year our website devoted exclusively to clinical trials was developed. This site contains all minutes of the monthly Bay Area Breast Cancer Forum, monthly newsletter articles, annotated websites of interest, a comprehensive listing of all breast cancer clinical trials available at UCSF, according to eligibility requirements. We will soon add a comprehensive glossary of terms.

Task 7
During the second year, we have created a clinical trials poster and brochure directly aimed at informing diverse and underserved women about their eligibility for and availability of clinical trials here at UCSF and at other sites locally. These materials will be distributed to primary care physicians, oncologists and surgeons offices, mammography suites, senior centers, and support groups. Versions in Spanish, Russian, Chinese and Japanese will also be developed. Two members of our Spanish speaking staff, one Japanese speaker, and one Russian speaking staff member will conduct seminars using a newly developed slide presentation geared to education on breast cancer and clinical trials. See Pilot A Outreach Projections attached. In addition, educational materials about clinical trials will be distributed to patients at the Forum, during Speakers' presentations, and at the Tumor Board. Informative articles that relate to the monthly Forum topic are included in a Bibliography section of the website.

Task 8
For the past 18 months we have enjoyed increasing success with our Forum, a monthly gathering of patients, health care providers, patient advocates, family and friends. Our attendance is generally about 45 people, with a mailing list of 250. The topics range from clinical trials and the future of research, to genetics, to alternative medicine, to how to read your pathology report. Some topics of more than general interest have actually evolved into their own projects. A few examples are listed:
- A patient navigator Program which has received start up funding from the Department of Medicine and will be enrolling patients in the next month
- An advocacy-led Integrative Medicine Seminar
- A "Breast Cancer 101" course that was very well attended by the BCC staff and patients/advocates.

We have also begun monthly clinical trials updates to caregivers during weekly Tumor Board and are making clinical trials lists available to care providers in the community.

Our plan for year 3 is to develop more involvement with the diverse communities of the Bay Area by producing information evenings for members of the Latina, Russian, and Asian communities. Physicians who are bilingual in each of these languages will preside over the group. Information will include a slide presentation about clinical trials and breast cancer, and leaders will try to elicit information on why participation is traditionally low in minority communities. This intervention will lead to the design and initiation of trials which will be of greater interest to these patients.

Conclusion

We have completed an assessment of barriers to clinical trial enrollment from both providers and patients, and have analyzed the data to determine important barriers as they pertain to specific care providers/patients subsets. Our education and outreach program to patients and care providers is being rolled out ahead of schedule and more broadly than originally planned. We are focusing our efforts on minority outreach by creating and distributing flyers, posters and brochures to physician offices, mammography centers, support groups, anywhere that our target audience may see them. We have created a website which is linked to many breast cancer information and support sites where patients and families can get information regarding ongoing clinical trials at UCSF. Evening information forums will continue, with additional slide presentation evenings devoted to the importance of clinical trials for the underserved in our communities. As our baseline clinical trial enrollment is already more than double the national average, we are in need of these expanded programs to further improve this number, and to provide us with the information we need to develop trials that are more interesting and relevant to patient concerns.

Conclusion

Year 2 of the grant solidified the basis upon which the next two year's work will be built and enabled us to refine the structure of our efforts.

As we move into Year 3, we look forward to the implementation of all the processes we have developed. Education of physicians and patients and integration of all of our surveys will provide us with meaningful feedback about how to continue improving our services. One key program which will stand as an example for future projects will be our Same-Day-Evaluation program, complete with informatics/key data element capture, the reorganization of services and the tracking of costs. This will require a close collaboration among Informatics, CQI, Administration and Education Cores and Project 1. The implementation of the Same-Day-Evaluation program will start October 1.

Another priority will be the coordination of surgery, pathology and research tumor banks, the common marking of specimens, the coordination of the use of trials, notification of tumor banks, pathology & research tracking sheets and the data for the micro-metastases project. Additional focus will be on the coordination of integrated trials for Stage III disease. The CQI Core will focus on the implementation of the follow-up program that will gather data as a basis for interventions, standardization of forms and procedures, availability for new patient appointments, improved efficiency, and cost effectiveness.

Future services planned for Year 3 also include second opinion consultation recording and providing a personalized, written record for patients, which would include decision processes, treatment options and clinical trials available.

The enthusiasm among our staff continues to grow as the integration of our projects come together in a cohesive model. We have added monthly PI meetings in addition to the quarterly grant meetings to improve integration of the cores and projects. We enter Year 3 with high expectations of continuing our progress and exceeding our goals.

Appendices

B.C.

August/September 1998

The B.C. Newsletter provides bi-monthly information for patients and staff at the Carol Franc Buck Breast Care Center.

SPOTLIGHT: *Chinese Herbal Therapy Study*

Dr. Debu Tripathy and researchers at the UCSF Medical Center are conducting a study to assess the feasibility of using Chinese Herbal Therapy to alleviate the side effects of chemotherapy.

This is a randomized, double-blind, placebo controlled study -- patients will have an equal chance of getting the herbal therapy treatment or an inactive placebo.

Patients are eligible to participate if:

- they have completed surgery for Stage I or Stage II breast cancer,
- they are not using herbal therapy now, or are willing to discontinue all current herbal treatments three weeks before starting the study, and
- the patient's doctor has recommended AC chemotherapy.

Fur further information, or if you are interested in participating, please call Erika Leemann at (415) 885-7328.

From: Not Now, I'm Having a No Hair Day! -- Humor & Healing For People With Cancer, by Christine Clifford. See: Bookshelf, page 6

INTRODUCING NEW STAFF MEMBERS!

✯ *Judi Allen, AAIII*

Judi, Dr. Laura Esserman's new Administrative Assistant, worked at Genentech for the past fourteen years as an Executive Assistant. She is a breast cancer survivor and patient advocate who first learned about our center when she came to see Laura for a second opinion and was immediately impressed by the BCC's work and commitment. Judi subsequently organized cancer awareness seminars for the staff at Genentech; she also coordinated Laura's work on the Her2 study. Judi enjoys the challenge of helping Laura meet her mission objectives and optimize her time and efforts; in fact, she calls herself a "professional border collie".

She shares her home with a Marmaduke-look-alike dog named Elsa and spends her free time at her cabin in Lake Tahoe. She has a grown-up daughter who is a successful Director of Advertising & Promotion at a large company.

Judi will be participating in the upcoming "Race for the Cure" and invites everyone at the BCC to walk with her or to volunteer at our booth! (See announcement page 7.)

✯ *Henry Mark Kuerer, MD-PhD*

Henry Mark Kuerer joined our team of breast surgeons at the beginning of July. Dr. Kuerer graduated cum laude from Rutgers College, N.J., with a B.A. in Biological Sciences. He obtained his M.D. and Ph.D. at SUNY Health Science Center, N.Y., and completed his general surgery residency at the Mount Sinai School of Medicine in New York City. Subsequently, he moved to Houston, Texas, for his fellowship in Breast Surgical Oncology at the M.D. Anderson Cancer Center. Recently, he received an American Society of Clinical Oncology Merit Award.

While he's only been in San Francisco a month, he says he really loves the City and is glad to be here.

✯ *Erika Leemann*

Clinical Research Associate

Erika graduated from Carleton College in 1994 with a degree in English literature. She came to the Bay Area to work as a volunteer at a community clinic, the Native American Health Center. She still works part-time at the clinic and is also in her second year of a post-baccalaureate pre-medical program at Mills College.

Erika will be working on the Chinese Herbal Therapy study, and is looking forward to learning more about building bridges between Western and alternative therapies.

She lives in Oakland, and enjoys singing, writing, reading, and the outdoors. She is currently working on becoming monumentally well-informed through hours of NPR listening on the Bay Bridge each day.

✯ *Michael Patterson*
Program Manager -- Complementary and Alternative Medicine Program

Michael joins us from the State of California Department of Health Services in Berkeley, where he worked as a Program Specialist, overseeing a number of State-wide genetic service programs, most recently the Hemoglobin Trait Follow-up Program. While Michael is a genetic counselor by training, he also has a background in alternative medicine. For the last five years Michael has been a certified massage therapist and has his own part-time practice.

Michael is excited to be combining his more traditional medical training and his alternative medicine interests into his new position. Michael is 50% employed by the Breast Care Center and 50% by the Osher Center for Integrative Medicine, where he will be working in their Complementary and Alternative Medicine Clinical Trials Unit.

Michael interests outside work include travel, hiking, theater, singing, and his current obsession: trying to eat at all of the great restaurants in San Francisco (any suggestions are much appreciated)!

✯ *Priti Patel*
Data Assistant II

Priti has lived in San Francisco for fourteen years. She graduated from San Francisco State University in May of 1998 with a B.S. in Cell and Molecular Biology. Currently, she is working with Gigi Medan on the BCC Clinical Database, and she enjoys the friendly atmosphere here. At some point in the future, Priti is hoping to attend graduate school in Pharmacy or Research. Her hobbies include reading, hiking, drawing, and shopping.

(And for those of you wondering about her relationship with Kiran Patel, she is his sister-in-law ...)

✯ *Annette Ramos*
Medical Assistant, BCC

Annette previously worked at the CPMC OB/GYN clinic and in a OB/GYN medical group in Burlingame. She graduated from USF with a BSN two years ago and is expecting to get her nursing certification later this year; a goal which got postponed because she got married and had a baby boy since her graduation.

Annette's main professional interest is in women's health and oncology. She enjoys the challenge of remaining cheerful in a sometimes very tense environment and extending compassion and an open ear to patients in crisis. "I want to show them there is always a tomorrow!"

✯ *Michelle Williams-Jones*
AA, BCC Front Office

Like many of our employees, Michelle started out at UCSF working for the temp pool. She completed assignments at the Brain Tumor Research Center and at Mt. Zion Home Care before joining the Breast Care Center in October. She became

a permanent employee here at the end of June.

Michelle enjoys working here and learning more about cancer and the options for treatment. She hopes this knowledge would enable her to assist friends or family members who might face the disease one day. She also finds the BCC location extremely convenient, since she has a ten-year old son who attends school at St. Dominik's, as well as a five-year old girl in pre-school in the Marina.

In her free time, she really enjoys arts & crafts; she sews a lot and is skilled at creating dolls. She has also joined the Mt. Zion Hospital Bowling League and is working on perfecting her bowling skills!

A New Vision For Integrated Breast Care

In 1996, as most of you know, we were awarded a multi-million dollar grant to fund "A New Vision for Integrated Breast Care", a joint program between UCSF and CPMC. Our mission is to establish an innovative setting that will better meet the needs of clients with breast disease by gathering specialists involved in all aspects of breast cancer at one site.

Infrastructure

The grant infrastructure consists of *four Projects and one Pilot Project,* all of which are working towards specific aims. The Projects are assisted by several *Cores:* the Administrative Core, the CQI (Continuos Quality Improvement) Core, the Informatics Core and the Education Core.

NEWS FROM THE GRANT

The **Psychosocial Program**, Project 2 of the DOD Grant, continues to accept participants in their research program. They are investigating two approaches to providing care for women living with breast cancer: a Life Issues Support Group and an Integrated Support Program.

Women in the Life Issues Support Group will participate in a 12-week support group emphasizing coping with life issues, such as communication, methods of coping, and emotional expression.

Women in the Integrated Support Program will join a support group, a health education program, and a stress management program incorporating techniques such as yoga, meditation, and guided imagery.

Participants will be randomized to either of these two interventions. They will be asked periodically to fill out questionnaires assessing quality of life and coping style over the course of one year from study entry. This research trial is FREE and open to all women in their first eighteen months since diagnosis with primary breast cancer or women living with recurrent or metastatic breast cancer.

The program is led by Elisabeth Targ, M.D. and Ellen Levine, Ph.D. For more information, please call (415) 885-7877.

❀ BREAST CARE: NEWS YOU CAN USE

Early chemotherapy before cancer surgery may save breast

July 30, 1998, Dan Rutz (CNN) -- Chemotherapy treatment for breast cancer patients several months before surgery may mean the difference between losing a breast to the disease or undergoing a less extensive operation, according to a new study. The study, published in the August issue of the Journal of Clinical Oncology, finds chemo-therapy several months before surgery shrinks breast tumors by more than half, in eight out of 10 patients.

"This study is a new approach to the treatment of early and middle-stage breast cancer," said Dr. Bernard Fisher of Allegheny University of Health Sciences. The study indicates more women, including those with large tumors, might be able to safely undergo conservative surgery that cuts away a tumor rather than completely removing a breast. Delaying the operation for chemotherapy treatment does not appear to increase the risk of cancer relapse. "It can be used in any woman with the understanding and the total freedom that she's not being shortchanged by this kind of therapy," Fisher said.

THE BOOKSHELF

The BCC's Book-of-the-Month:

Fine Black Lines -- Reflections on Facing Cancer, Fear and Loneliness, by Lois Tschetter Hjelmstad

Breast cancer is an experience that produces change in a woman's life which is often profound, sometimes subtle. Whatever a woman's response, it forcefully causes her to focus on issues of mortality, self-esteem, survival, sexuality, and other things that give substance and meaning to live.

Fine Black Lines, at once sensitive, funny, poignant, angry, earthy and transcendent, is an expression of deep spirituality that surges far beyond religious doctrines into the realm of personal faith. Courage shines through, as well as curiosity and compassion.

❀

Living Beyond Breast Cancer -- A Survivor's Guide For When Treatment Ends and the Rest of Your Life Begins by Marisa Weiss, M.D., and Ellen Weiss

With the progress we are seeing in early detection and the increasingly effective treatment of breast cancer, more women are surviving longer. But patients who finish treatment continue to be anxious. Am I really cured? Is it safe for me to get pregnant? Can I take hormones? Will my cancer diagnosis affect my ability to get health insurance? Patients need intelligent, in-depth responses.

Living Beyond Breast Cancer is a comprehensive, practical, sensitive, and extremely useful guide for women looking to take care of their health and well-being once the crisis is over and the next phase of their lives begins.

Not Now, I'm Having a No Hair Day! -- Humor & Healing For People With Cancer, by Christine Clifford
Christine Clifford reaches out to people with cancer from her own experience with surgery, radiation, and chemotherapy. Convinced that laughter can bring healing, she takes a light-hearted look at the trials people face during diagnosis and treatment.

The book features humorous cartoons by Illustrator Jack Lindstrom and is a terrific book for patients with cancer and their loved ones.

Better Bones, Better Body -- Beyond Estrogen and Calcium by Susan E. Brown, Ph.D.

Excessively thin bone, known as osteoporosis, is the most common bone disorder in the United States. An estimated seven to eight million people in the United States have osteoporosis, and another 17 million are at high risk for the disease due to low bone density. Overall, half of all Caucasian American women aged 50 will suffer one or another osteoporotic fracture during her lifetime.

Better Bone, Better Body features a comprehensive self-help program, challenging current assumptions and moving away from superficial explanation to a deeper understanding of the problem of osteoporosis. Susan Brown does a great job of presenting information in a useful way to help reader make practical decisions about diet, exercise, medical tests and therapies.

CALENDAR

BREAST TALK

Please join us for a Special Talk by Peter Ravdin, M.D., University of Texas, San Antonio, on "Shared Decision-Making and Early Stage Breast Cancer", **Monday, August 24, 11:30am,** at the **Cancer Center, 3rd Floor Conference Room.**

Dr. Ravdin will also discuss new therapies for advanced breast cancer at 8:00am at UCSF Parnassus Campus, Room M-1296.

For more information, contact Fern Hassin at (415) 885-3738.

***BENEFIT:** for the **Psychosocial Program** (see page 4):*
Saturday, August 29, 3-7pm at El Rio, 3158 Mission St. (at Army)
$8 donation requested, but no one will be turned away.

CONFEERENCE: Supportive Care For People With Cancer
Friday, September 18, 1998, 10am-12noon
Herbst Hall, UCSF/Mt. Zion Hospital, 2nd Floor
Light snacks/refreshments
Free & open to the public!

This conference will present ways in which the medical team, in conjunction with a comprehensive cancer rehabilitation program, can complement standard cancer treatments. Speakers will discuss strategies to promote active

participation in supportive care to improve the mental and physical status of cancer patients. The conference is geared towards medical professionals, patients, and families.
Speakers will include Charlotte Jacobs, Director Clinical Cancer program; Ernest Rosenbaum, MD; Andrew Kneier, Ph.D.; Cindy Perlis, Art for Recovery; and Keren Stronach, Coordinator of the Cancer Resource Center.

BAY AREA CANCER MARCH

Participate in the Silent March, bring your own sign or make one at the poster station, bring photos, poems, writings and other memorabilia to put on the "Wall of Hope" display, and sign the Cancer Bill of Rights. Thursday, Sept. 24, 11:30am - 1pm, Union Square, San Francisco. For more information, call (415) 458-4668.

SYMPOSIUM: Research Challenges in Integrative Medicine -- Toward a New Science of Healing

The Osher Center for Integrative Medicine presents an afternoon symposium on September 25 at Cole Hall. For more information, call the Center for Integrative Medicine at (415) 502-0285.

PEAK HIKE 98 SEPT. 26 & 27

The Breast Cancer Fund will host its third annual Peak Hike, a challenging 10-mile day-hike on Mt. Tamalpais. Led by breast cancer survivors and others who support the cause, the hike will raise money for patient support services, education and advocacy efforts. **Help us form a Breast Care Center team that will participate in this hike and enjoy one of the most spectacular trails in the Bay Area!**

For more information, please call Meridithe Mendelsohn at 885-7558.

MARK YOUR CALENDARS!
RACE FOR THE CURE OCT. 18!

Save the date to walk/run for UCSF! We are aiming towards a new record number of participants in our team! Also, we still need a FEW GOOD WO/MEN to work with us at our booth on the actual day of the race. Small commitment, lots of fun!

Don't hesitate, call now! Contact: Kristie Dold at (415) 885-7801.

EMPLOYEE OF THE MONTH!

The award for July 1998 went to **Meridithe Mendelsohn** for always smiling and remaining calm, (despite the enormous amount of work on her plate); for being a shining example of an excellent employee, (working hard & taking on projects that are difficult); for being a role model, a confidante, an excellent chef; and for always remembering the big picture, despite the daily frustrations.

August 12, 1998/sp

(Brochure text -- brochure in process of being printed)

BREAST CARE CENTER

The Carol Franc Buck Breast Care Center at the Cancer Center is specifically designed to meet the needs of patients with breast problems, breast cancer, or general concerns about breast health. Our multidisciplinary team works with you individually to help coordinate your care and minimize your visits to the Cancer Center.

OUR SERVICES INCLUDE:

- breast examinations and mammography
- breast self-examination training
- second-opinion service for women with a cancer diagnosis
- evaluation and diagnosis of lumps, abnormal mammograms and other breast problems
- surgery, radiation, medical oncology and plastic surgery
- emotional support, including individual counseling, support groups, and patient support networks
- family and risk assessment counseling and genetic testing services
- financial and insurance counseling
- a comprehensive **Resource Center**, providing instructions and access to the latest computerized medical databases, the Internet, and CD-ROMs. The Resource Center provides an expanding library of books, articles, audio- and video-tapes. Topics include nutrition, relaxation, conventional and alternative treatments, inspirational accounts and coping strategies.
- a program for lifestyle support and nutrition counseling
- referrals for pain management, including trials for herbal medicine and acupuncture
- hormone replacement therapy consultations in relationship to breast care issues
- education programs for patients, family, and friends

OPENING SOON:

- a healing garden and adjacent cafe providing healthful snacks, meals and cooking demonstrations
- a boutique with surgical specialty bras, prostheses, wigs, scarves, and books.

FOCUS ON THE INDIVIDUAL - THE WHOLE PATIENT

We have been awarded a multi-million dollar grant to fund "A New Vision for Integrated Breast Care", a joint program between the University of California at San Francisco (UCSF) and California Pacific Medical Center (CPMC). The Bay Area Breast Care Program (BABCP) was one of three sites chosen nationally for this prestigious grant.

Our mission is to develop an innovative setting that will better meet the needs of clients with breast disease. For this reason, we frequently invite people to participate in our research efforts to improve our process. By gathering specialists involved in all aspects of breast cancer, we are creating a patient-friendly, cost-effective, state-of-the-art breast care facility.

RESEARCH:

In addition to state-of-the-art clinical care, our physicians and scientists conduct research to:

- investigate the fundamental causes of breast cancer at the genetic, environmental and lifestyle levels
- understand what can be done to prevent cancer or to diagnose it as early as possible
- analyze the biology of cancer to develop innovative strategies for treatment
- test and evaluate new treatments, whether in the area of conventional medicine, novel biological drugs or alternative medicines
- integrate patient decision-making and psychosocial support.

The Breast Care Center team is actively involved in public policy development, focusing on issues surrounding mammographic screening, genetic testing, and the appropriate and timely evaluation of new treatments.

We are dedicated to working collaboratively with all who seek our services, especially in the areas of education, clinical trial participation, advocacy and research. We appreciate the value of your opinions, feedback and new ideas.

Statements of Work- CQI Core

Overall Objectives

- Finalize process and outcome measures for the BCC
- Continue to evaluate current processes and identify those most in need of CQI intervention.
- Identify and implement process for elements of work that should be routine and consistent among practitioners, and those whose variation should be encourage and tested.
- Develop CQI instruments to track/assure that patients are given clinical information that is data driven and consistent with principles of evidence based medicine, but have the flexibility to make choices consistent with their values.
- Assure that the Breast Care Center continues to meet the patients needs.
- Provide feedback to individual providers (BCC staff) on their own activities relative to their peers and on all aspects of information available to the CQI group.

Specific Tasks for Year 2 (some tasks will roll over to year 3)

C1.1 Choose clinical and medical outcome measures to be used as the "report card" for the Breast Care Center. These measures must reflect the needs of the patients, the physicians, health plans, and employers.
C1.2 Establish patient navigator program
C1.3 Create a new follow up program
C1.4 Hold a patient a series of forums to address the issues of quality according the patient
C1.5 Identify hierarchy of values of patients and providers regarding treatment decision making
C1.6 Create survey instruments for staff and MDs to fill out regularly to identify areas where improvement is needed.
C1.7 Tracking and then identifying improvements on the time it takes to perform a wire localization procedure.
C1.8 Creating patient satisfaction surveys
C1.9 Coordination all surveys and activities

III.B.1.d. Statement of Work

CQI CORE

Activities that will foster both the process and the outcome goals of CQI must be used together to meet the goals for this core. Throughout the four years of the project, staff from the Laboratory for Intelligent Learning will assist members of the CQI core in assessing the role and function of the CQI teams vis`a vis Breast Care Center faculty and staff, the UCSF Cancer Center, the Medical Center as a whole and the University. LIS will use the tools available to them to develop group process skills in order to achieve the outcomes desired for each year. (See Stanford MOU for details, Addenda III-B.3.e.)

YEAR ONE

1. Establish a common medical record among practioners in the BABCC
2. Establish a method to arrange coverage for the Breast Care Clinic.
3. Develop a plan to obtain patient follow-up information.
4 Establish a system to assure long-term patient follow-up.
5. Establish a plan for the use of fine needle aspiration.
6. Establish a role for use of stereotactic biopsy.
7. Hire/train analyst to have day to day responsibility for CQI activities
8. Develop goals, mission statement

YEAR TWO

1. Study reasons for delay in the detection of breast cancer in minority women.
2. Adopt strategies to reduce utilization of formal axillary node dissection.
3. Adopt a standardized method of physical breast examination.
4. Develop a consensus on use of hormone replacement for patients with breast cancer.
5. Work with informatics core to get information from Clinical Information System in format that will facilitate CQI process

YEARS THREE AND FOUR

1. Develop a plan to distribute cancer tissue samples to other research programs.
2. Design a strategy for care of patients with advanced breast cancer.
3. Evaluatie data from CQI core and Education core and develop triggers to be part of on-line decision support for the clinical information system
4. Identify operational processes that require improvement, appoint individuals to work and devleop interventions, test and reassess data (will be done each year)
5. Clinicians will identify and prioritize clinical treatment strategies for analysis, and work with informatics core to collect data real time and monthly for presentation and analysis in CQI team. Identify variation in practice and associated outcomes.Design interventions and reassess
6. Develop performance criteria with the Administration Core

INFORMATICS CORE

Glossary

- **CCS**: the Clinical Communications System described in this application
- **CES**: UCSF's Clinical Enterprise Systems Department, formerly the Hospital Information Systems Department

YEAR ONE:

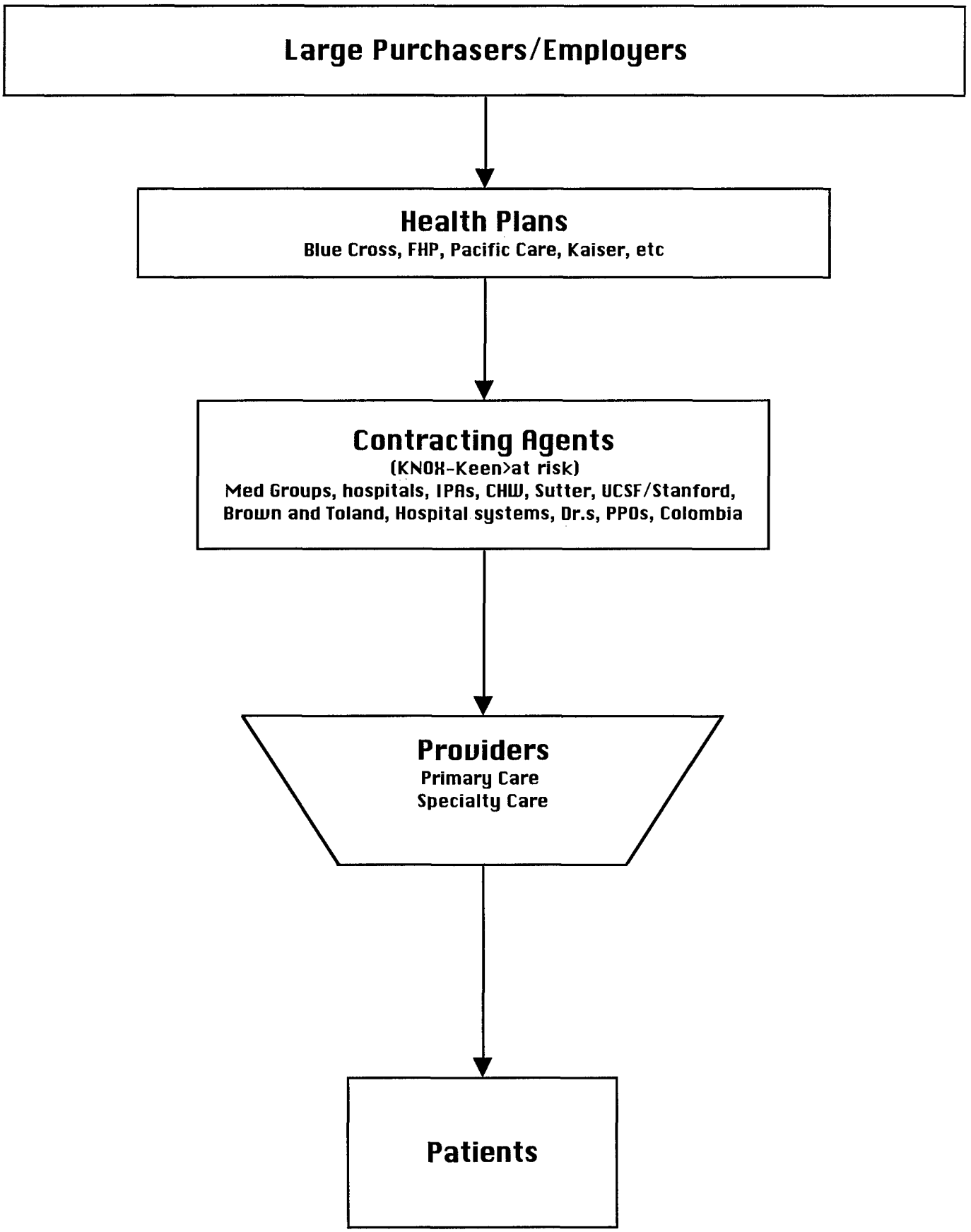
- CCS: Implementation of pilot project in Breast Care Center
- CCS: interfaces to CES systems started
- Evaluation and enhancement of current research databases
- Evaluation and design of new clinical research databases

YEAR TWO:

- CCS: Automation of all breast cancer treatment plans and protocols
- CCS: Evaluation and design of cost capturing capabilities
- Ongoing design and maintenance of clinical research databases

THE FOOD CHAIN

who eats who?



The Food Chain Table

By better understanding the stakes and major issues of concern to each of the parties, we hope to develop a strategy for developing a Quality Report Card that will have an impact

	Certifiers	**Quality Measures**	**Levers to Change** (things that could be)	**Who is held accountable?**	**Priorities**
Large Purchasers/ employers	NCQA, PBGH (?), JCAHO (?)	Employer groups, Hedis, FAcct, RAND pilot	• Information on quality-wellness productivity • Cost	Health Plans	
Health Plans	NCQA	Hedis	• Alignment of wellness and productivity with health benefits • Cost		
Contracting Agents	JCAHO, FDA	Accredidation by JCAHO	Arrangements: • KNOX-Keen • fee for service	individual physicians (?)	

Providers	CMA, MD, Academic centers, BMQA, MBC,	Medical Board,pt. satisfaction, morbidity, mortality	Provider access	hospitals(?)	
Patients		pt. satisfaction, morbidity, mortality	• consumers empowered w/information • Women make health care purchasing decisions	Providers and health plans	

- **We also need to consider other influences such as advisory groups, regulatory bodies, and public action groups because they are often an important influence on how the food chain is managed.**

BCC ENCOUNTER FORM SUBMISSION RATE BY PROVIDER

PROVIDER	WEEK 5/11	WEEK 5/18	WEEK 5/25	3 WK AVG	WEEK 6/1	WEEK 6/8	WEEK 6/15	6 WK AVG RETURN RATE
1	67%	100%	100%	89%	out	out	out	**89%**
2	85%	48%	84%	72%	78%	68%	89%	**75%**
3	OUT	100%	OUT	100%	100%	100%	100%	**100%**
4	47%	36%	80%	54%	85%	60%	67%	**61%**
5	67%	62%	75%	68%	36%	70%	82%	**66%**
6	44%	0%	25%	23%	31%	27%	77%	**32%**
7	NA	NA	NA	na	NA	NA	NA	**NA**
8	86%	80%	OUT	83%	100%	86%	84%	**87%**
9	OUT	OUT	OUT	na	100%	100%	100%	**100%**
10	83%	71%	93%	82%	82%	75%	80%	**81%**
11	59%	62%	OUT	61%	0%	100%	62%	**57%**
			AVERAGE	**70%**				**75%**

SUBMISSION RATES BASED ON RETURN TO FRONT OFFICE BY 5PM ON DATE OF SERVICE

UCSF Breast Care Center
PATIENT NAVIGATOR PROGRAM

Patient Navigator Training Manual
1998

Introduction

We are pleased to welcome you to the Patient Navigator Program of the UCSF Breast Care Center. The Patient Navigator Program has been established to help women cope with and manage the many challenges they face once they are diagnosed with breast cancer. As a Volunteer Navigator, you will have a crucial role in the success of the program, and we are extremely pleased that you have decided to make this very important commitment. We hope that you will find this a worthwhile and rewarding experience.

As a Patient Navigator, you are modeling: a) that it is possible to cope effectively with illness and treatment, b) that it is possible to return to significant functioning, and c) that it is possible to survive breast cancer. We recognize that it is important for you to have a clear idea of your role and your purpose. Our training has been designed to provide the necessary information, tools, and techniques to help you be successful.

As a trained volunteer who has had cancer and has received treatment, you will be part of a team, there to help make things more manageable for new patients. Should you note problems, you will be able to assist by bringing these problems to the attention of the doctors and/or staff. When problems arise, our goal and your goal will always be to find ways to improve the system at the Breast Care Center, so that patients get the best possible care. As a Navigator Volunteer, you will also be there to answer questions about your experience when appropriate: what it was like for you, how you managed, what worked, what did not. (Of course, you will always keep in mind the importance of maintaining appropriate boundaries and not giving out medical or psychological advice.)

As a Patient Navigator, you will learn how to be sensitive to the fact that each experience is different, each person is different, each disease is different, each interaction is different. You will, therefore, become skilled listeners, learning how to let the patient take the lead, learning how to start where the patient is at, and learning how to make no assumptions as to the major concerns.

Listening Skills

Listening

Listening is one of the most important gifts we can offer. Often, it is the only thing we can do to help another person.

1. The goal of listening:

- to help the other person understand his/her own experiences and feelings.

The best way to do that is to listen openly to what the person says.

2. What gets in the way of listening:

- we start to feel uncomfortable
- we start talking
- we listen for too short a time
- we make judgments about the person and his/her problem
- we try to problem-solve or fix
- we focus too much on content rather than feelings
- we take action too quickly (to make a problem or feeling go away)

Supporting

Supporting a person involves 3 key elements:

- attention
- recognition
- validation

Supporting a person does not involve solving his/her problems or changing his/her feelings or experiences.

Paraphrasing and Reflecting Feelings

It is very important to all of us to know that we have been heard and understood. In combination, paraphrasing and reflecting feelings are two ways to achieve this.

1. Paraphrasing:

- taking the content of what a person has told you and repeating it in your own words.

2. Reflecting Feelings:

- taking the feelings and experiences of another person and reflecting it back as you understand it.

Paraphrasing and reflecting involve:

- paying attention to non-verbal cues (expressions, tone, intensity, etc.)
- connecting the content, feelings, and non-verbal cues to create a meaningful understanding of what the key issues are
- asking appropriate and relevant questions (i.e., staying where the person is)

Questioning

Open-Ended Questions:

Open-ended questions are questions that cannot be answered with one or two words. As a result, they open up communication and encourage the person to talk. These type of questions will often lead to deeper thoughts and feelings.

Open-ended questions usually begin with how or what.

Example of an open-ended question:

- What has your doctor told you about your treatment options?

(The person will most likely beginning telling you what she remembers hearing from her doctor.)

Example of a closed question:

- Will you be having chemotherapy?

(This type of question allows for a yes/no response and does not encourage more conversation.)

Sample Open-Ended Questions:

To Begin A Conversation:

- What would you like to talk about?
- What is going on today?

To Clarify or Elaborate:

- How is this a problem for you?
- What do you mean by.....?
- What bothers you about the situation?

To Talk About Feelings:

- How do you feel about that? (Make sure you get a feeling answer.)
- What is (a feeling) like for you?

- How do you feel right now?
- What would you like to say to him/her? (Helps people get in touch with feelings about other people.)

To Help Problem-Solve:

- What options do you have?
- What have you thought of doing?
- How do you feel about each of these options?
- What's the best thing that could happen? the worst thing?
- What do you think will actually happen?

When You're Not Sure What the Person is Saying, ask for clarification and/or elaboration:

- What do you mean by....?

Example: Patient: "There's no one who can help me with this."

The patient may be saying any number of things. A few might be:

- I have no support.
- The doctors tell me there is a high probability that I will have a recurrence.
- My family doesn't want to talk about this.
- I can't get through to my doctor on the phone.

A clarifying question is essential to understand what the person means.

How To Question

- Ask questions that are clear and simple.
- Avoid long, complicated questions.
- Keep questions in the here and now.
- Ask appropriate and relevant questions. (Do not ask questions to satisfy your own curiosity.)
- Avoid asking questions that begin with the word why. (This can often sound judgmental and raise a person's defenses.)
- Be very careful that you do not mask advice in the form of a question. (Example of masking advice with a question: Don't you think it would be a good idea to use the relaxation tape during your chemotherapy treatment.)

Other Helpful Hints:

- Allow Shades of Gray

- Using words and phrases that are provisional (not absolute) when speaking with another person can minimize defensiveness and leave room for possibility. In other words, it can encourage a variety of thoughts, opinions, feelings, creativity, and problem-solving.

- Provisional words and phrases include:

probably	perhaps
on the other hand	it seems unlikely that
occasionally	sometimes
tends to	it may be that
it could	generally

Sharing Personal Experience

Self-disclosure may help the person feel safe and more trusting. However, it is very important that you monitor how much you disclose and what the tone of that disclosure is.

Before sharing your own experience, check in with yourself. Ask yourself these questions:

- Why am I choosing to tell this now?
- Am I feeling uncomfortable about something?
- Am I using this to steer away from something?
- Is it appropriate and relevant to the discussion?

If you do choose to share something about your own experience, return to the other person's feelings immediately after any self-disclosure.

Silence

For some, silence can evoke tremendous anxiety and feel terribly scary and unsafe. For others, silence can be profoundly healing, intimate, rich, and real. Allowing silence often leads to further disclosure. Make every effort to sit with a person's silence (including your own!)

Some Do's and Don'ts

Do's

- Listen and encourage the patient to do the talking.
- Answer questions as honestly as possible. Use your personal experience when appropriate, emphasizing the uniqueness of each person's experience.
- Be alert to the patient's needs beyond the initial statement of the problem, yet always deal specifically with the need or problem the patient has expressed.
- Keep in mind that the patient might be angry, anxious, and frightened.
- Refer medical questions to the patient's physician. Help the patient articulate the questions.
- Keep all information confidential. No information, names, medical condition, or person information is to be divulged to anyone without the patient's approval.
- Use a problem-solving, positive approach to patients, concerns by sharing how you were able to cope with situations and hospital personnel or resources which are available to help.
- Alert the Patient Navigator Coordinator, Dr. Debra Marks about any problems, observations, or occurrences with patients which concern you or which you do not understand.
- Refer patients to the Patient Navigator Coordinator, Dr. Debra Marks, if there are concerns relating to patient care or hospital/staff issues.
- Take care of yourself. Emotional issues can surface for you. Call Dr. Marks to check in, share your experiences, or to express concerns or questions (yours or the patient's.)

Don'ts

- Do not share more information than people request. Meet patients where they are and provide only the necessary information to help them with expressed concerns so as not to overwhelm them or raise unnecessary problems.

- Do not give statistics on any aspect of cancer treatment or survival. Answer questions only from your own experience and encourage them to ask questions about their own unique situation.

- Do not compare the patient's progress with yours or others or detract from the patient's concerns by discussing your own illnesses or problems.

- Do not attempt to cheer up the patient or say such statements as don't worry or I'm sure it's nothing serious.

- Do not give in to your own personal responses to personalities or to conflicts between patients and their family members. When confronted with a difficult personality or situation, refer the patient to the Navigator Coordinator.

- Do not give medical advice or interfere with the physician/patient relationship or imply criticism of medical treatment a patient is receiving or has received. (However, if you have a problem or concern, discuss this with Dr. Marks.)

- Do not impose your own values or biases on the patient, such as specific religious beliefs, dietary practices, etc.

- Do not be a cheerleader or critic of UCSF/Mount Zion Medical Center or any individual health care professional. Remain neutral.

- Do not encourage people to make specific choices or decisions about treatment.

Psychosocial Issues

The Patient

Being diagnosed with breast cancer (or any life-threatening illness) involves many losses. Some are temporary. Others are more lasting. Temporary losses may include loss of independence, loss of a breast, loss of overall health and well-being, loss of ability to work, etc. A more lasting loss involves the loss of the illusion of safety.

Most of us walk around feeling relatively safe in the world. We do not focus on the fact that we could get run over by a car, be shot, be hurt, die unexpectedly, etc. If we did, we would be overwhelmed with anxiety and could not function. We block out these possibilities, and this blocking out is a healthy and adaptive defense to allow us to continue on with our lives.

When you have been diagnosed with cancer, that defense falls away. You are no longer able to maintain that illusion of safety in quite the same way. You are confronted with the reality of your own mortality, and it is often hard to stop thinking about it. Priorities change. Life gets re-evaluated. Relationships are impacted. Everything seems different.

Patients frequently speak about the need to stay positive, despite the fact that they often experience so much internal and external chaos after being diagnosed. As with any trauma, patients will experience a wide range of emotional responses. Disbelief, anger, fear, grief, anxiety, and depression are a few of the many reactions people face. These are all healthy emotions.

One way to think about what it means to stay positive: the ability to access and express your emotional life fully. (This is not only positive. IT'S HEALTHY!)

The Navigator

As a breast cancer survivor yourself, you may, at times, have strong emotions come up as a result of your work as a Patient Navigator. This is to be expected. You will be faced with situations and experiences that may remind you of your own ordeal. Old feelings may re-emerge. It is absolutely essential that you check in with yourself regularly about your own emotional responses. Since maintaining confidentiality is a very important responsibility of each Patient Navigator, you are encouraged to discuss your issues/concerns/feelings with Dr. Marks, who is available to help you sort through these responses as they emerge.

Common Terms

Abscess- An infection which has formed a pocket of pus
Adjuvant Therapy- Anticancer drugs used in combination with surgery and/or radiation as an initial treatment before there is detectable spread, to prevent or delay recurrence
Alopecia- hair loss
Axilla- armpit
Benign- not cancer
Calcifications- small calcium deposits in the breast tissue that can be seen by mammography
Carcinogen- substance that can cause cancer
Carcinoma-Cancer arising in the epithelial tissue (skin, glands, and lining of internal organs). Most cancers are carcinomas.
Colostrum- liquid produced by the breast before the milk comes in: pre milk
Contracture- formulation of a thick scar tissue, in the breast a contracture can form around an implant
Core Biopsy- type of needle biopsy where a small core of tissue is removed from a lump without surgery Cyst- fluid-filled sac
DCIS (Ductal Carcinoma in Situ)- ductal cancer cells that have not grown outside of their site or origin, sometimes referred to as precancer
Estrogen- female sex hormones produced by the ovaries, adrenal glands, placenta, and fat
Estrogen Receptor- protein found on some cells to which estrogen molecules will attach. If a tumor is positive for estrogen receptors it is sensitive to hormones.
Excisional Biopsy- take the whole lump out
Expanders- when an inflatable prosthesis is placed under the muscles of the chest wall and is gradually inflated with saline.
Fibrocyctic Disease- any benign condition of the breast
Hematoma- Collection of blood in the tissues.
Incisional Biopsy- taking a piece of the lump out

Invasive Cancer- cancers that are capable of growing beyond their site of origin and invading neighboring tissue. Invasive does not imply that the cancer is aggressive or has already spread

Latissimus Flap- flap of skin and muscle taken from the back and used fore reconstruction after mastectomy or partial mastectomy

LCIS (Lobular Carcinoma in Situ)- abnormal cells within the lobule which don't from lumps. They can serve as a marker of future cancer risk

Lumpectomy- the removal of a breast cancer (lump) and the surrounding tissue without removing the entire breast. It is a less-radical procedure than mastectomy and is usually followed by radiation treatment

Lymphedema- swelling, usually of an arm or leg, caused by obstructed lymphatic vessels. It can develop because of a tumor or as an usual late effect of surgery or radiotherapy

Lymph Nodes- oval-shaped organs, often the size of peas or beans, that are located throughout the body and contain clusters of cells called lymphocytes. They produce infection-fighting lymphocytes and also filter out and destroy bacteria, foreign substances and cancer cells. They are connected by small vessels called lymphatics. Lymph nodes act as our first line of defense against infections and the spread of cancer.

Malignant- cancerous

Metastasis- spreading of cancer to another organ

Microcalicification- tiny calcifications in the breast tissue usually seen only on a mammogram. When clustered, can be a sign of DCIS.

MRI- (Magnetic Resonance Imaging)- a method of creating images of the body using a magnetic field and radio waves rather than X rays. Although the images are similar to those of CT scans, they can be taken in all three directions rather than just in cross sections. There is no x-ray exposure.

Needle Biopsy (FNA)- removing a tiny bit of tissue for diagnosis by placing a needle into a tumor.

Neoadjuvant Chemotherapy- chemotherapy given before the primary treatment to improve the effectiveness of the treatment.

Oncogenes- Specific stretches of cellular DNA that, when activated in the wrong way, contribute to the transformation of normal cells into malignant ones.

Oophorectomy- the surgical removal of one or both ovaries

Palpable- can be felt

PET Scan- a new type of scan that detects areas of cells that are living and growing more rapidly than others. It may thus find areas of cancer by detecting their growth, rather than the space they occupy, as in CT or MRI scans

Placebo- an inactive substance, used in a research study or clinical trial, that looks like the medication. It is used to eliminate the improvement that may result from the belief that a medication is being given, rather than the actual effect of a medication

Progesterone- hormone produced by the ovary involved in the normal menstrual cycle

Prosthesis- artificial substitute for an absent part of the body

Punch Biopsy- a biopsy of skin that punches a small hole out of the skin

Quadranectomy- removal of a quarter of the breast

Sarcoma- cancer arising in the connective tissue

TRAM Flap (transverse rectus abdmoninus mycutaneous)- a portion of the vertical muscles in the center of the abdomen (the rectus abdominus) and a large ellipse of skin and fat from the lower abdomen are transferred onto the chest wall and shaped in the form of a breast

Radiation- external beams used to control the cancer. Can be used to destroy cells or shrink a tumor

Radical Mastectomy- removal of the entire breast along with underlying muscle and the lymph nodes of the armpit. In a modified radical mastectomy, the underlying muscles are left in place.

Remission- the partial or complete shrinkage of cancers usually occurring as the result of therapy. Also the period when the disease is under control. This is not necessarily a cure.

S-phase Fraction- measure of number of cells dividing at one time.

Subcutaneous Tissue- tissue under the skin

Systemic Treatment- treatment involving the whole body, usually using drugs

Tamoxifen- estrogen-like drug used in hormone replacement therapy

TNM Classification- a complex and exact system for describing the stage of development of most kinds of cancer.

** the above terms were extracted from both Susan Love's Breast Book and from the third edition of Everyone's Guide to Cancer Therapy

Tumor Board / Multidisciplinary Case Conference

The Tumor Board or Multidisciplinary Case Conference is a second opinion service offered at the Breast Care Center (BCC). Patients should be scheduled on Monday mornings for one hour with the physician presenting their case at the conference. Patients seeking a second surgical opinion should be scheduled with a surgeon. Patients seeking a second opinion about treatment should be scheduled with an oncologist. Patients seeking both can be scheduled with either a surgeon or an oncologist based on availability. Sometimes patients will see one of the physicians at the BCC during the week prior to the Tumor Board conference.

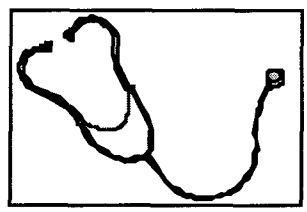
Chris Del Rosario coordinates Tumor Board. Notify her of any patients scheduled so she can contact them to obtain their medical records, any radiology films, and any pathology slides. Physicians are to complete the requisition form so Chris knows where to obtain the necessary slides and films. All of the above must be received by Thursday morning prior to the Tumor Board. Therefore, no Tumor Board patients can be scheduled after Thursday unless you speak with the doctor seeing the patient.

Sometimes patients being seen at the BCC will be presented at the Tumor Board by their attending physician to obtain additional treatment suggestions from their colleagues or to get ideas about clinical trails. These are scheduled according to the doctors discretion.

Depending on if films or pathology are reviewed by the appropriate departments, the patients fees for Tumor board will range from approximately $200 -$550. Some insurance companies will cover the cost and patients should call their insurance company.

Participants in the Mulitdisciplinary Case Conference

Many medical specialists participate in the diagnosis and treatment of breast cancer. Before the breast conference, you will be seen by one of the following experts:



SURGEONS provide information about the benefits and risks of surgery for the treatment and management of your breast cancer.

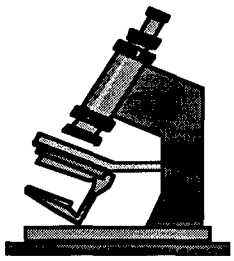
RADIATION ONCOLOGISTS provide information about the benefits and risks of radiation therapy for the treatment and management of your breast cancer.

MEDICAL ONCOLOGISTS provide information about the benefits and risks of systemic therapy, such as chemotherapy or hormone therapy, for the treatment and management of your breast cancer.

In addition to the above doctors, your case is discussed by one or more of the following experts:

RADIOLOGISTS read your mammograms, x-rays and scans, report any findings and recommend further diagnostic procedures, such as magnification views of the breast and/or ultrasound of the breast.

PATHOLOGISTS examine slides of your breast tissue taken during surgeries and biopsies under a microscope and report whether the tissue contains cancer or other relevant findings.



PLASTIC SURGEONS provide information about the benefits and risks of different reconstructive options.

GENETIC COUNSELORS provide information about the risks for developing breast cancer and related diseases and options for managing the risk.

PSYCHOTHERAPISTS (Social Workers, Psychotherapists) provide information about options for coping with the emotional impact surrounding the diagnosis and treatment of breast cancer.

NURSES attend the conference and raise concerns about patient care and case management.

Clinical Trials

If a patient asks you how to get more information about clinical trials, first tell them to mention this to their physician. In addition, they use these three sources for more information:

The Breast Care Center's web site: http://www.bcc-ct.his.ucsf.edu

BCC clinical trials manager: Seri Gomberg at 476-2096

The Cancer Resource Center can help them find clinial trials. Call 885-3693

General information number: 1-800-4-CANCER

Breast Cancer Resource Guide		
UCSF Breast Care Center		UCSF/Mount Zion Cancer Center; 2356 Sutter Street, 6th Floor
Front Desk	476-5555	Alternate phone number 885-3700; Fax Number 885-7218
Practice Manager: Laurel Bray-Hanin	885-7607	
Nurse Coord.: Deborah Hamolsky, RN, MS	476-5555	
Nurse Practitioner: Mary Lou Ernest, RNP	885-3736	
Psychological Consultant Debra Marks, PhD	885-7415 X42529	
Cancer Resource Center	885-3693	provides education, support groups, and programs
Genetic Risk Program	885-7779	Beth Crawford, MA and Peggy Conrad, MA
Surgery Scheduler	885-3524	Mary Garlit
Financial Counseling	885-3814	Room R104 in UCSF/Mount Zion Hospital
Breast Cancer Support Groups		
Personal Support & Lifestyle Intervention	885-7877	trial offering different types of support, including alternative modalities
Breast Cancer Support Group	388-3742	Cancer Support Community; Jane Kraft
DCIS Support Group	885-7415	Debra Marks, PhD
Support for Russian Speaking BC Patients	885-7415	Raya Smail, MA
Other Support Programs		
UCSF- Yoga with Jnani Chapman	885-3693	2330 Post Street, Suite 510; Thursday 12-1pm
UCSF- T'ai Ch'i	885-3693	UCSF Cardiac Care Gym; led by Alyce Bridges; Wednesday 12-1pm
Look Good, Feel Better	885-3693	a program of the American Cancer Society
Spiritual Counseling and Guidance	885-7786	
Healing Garden and Tile Making Wksp	885-3693	led by Ann Chamberlin
UCSF- Dance Class Mobilizing Spirit	885-3693	led by Anne Kranz
Art for Recovery	885-7221	Cindy Perlis
Community Resource Centers		
Community Breast Health Project	(650) 725-1788	770 Welch Rd., Suite 370, Palo Alto, CA 94304

UCSF/Mount Zion Cancer Center (SF)	885-3693	2356 Sutter Street, Second Floor, SF, CA, 94115
Marin General Hospital, Circle Center	925-7920	
Planetree Health Resource Center (SF)	923-3680	2040 Webster Street, SF, CA, 94115
Women's Health Resource Center (SF)	750-6500	3698 California Street, Ground Floor, SF, CA
Women's Cancer Resource Ctr (East Bay)	510-548-9272	
Free Services		
American Cancer Society (D. Moorehead)	394-7100	free hairpieces, breast forms, and transportation to treatment
Cancer Legal Service Project	989-1614	free legal assistance; insurance, employment, wills, etc.
Charlotte Maxwell Complementary Clinic	510-601-7660	free massage and other therapies for low income women
Look Good, Feel Better	885-3693	Free American Cancer Society Wksp to improve appearance during tmt.
Transportation Services		
Regional Transit	923-6070	discount card for disabled persons
American Cancer Society: San Francisco	394-7100	limited funds for taxis
American Cancer Society: Marin	454-8464	volunteers drive pts to appts in Marin, occassionally in SF
American Cancer Society: East Bay	510-832-7012	limited funds for taxis
Mike Mobile	661-5596	escort home from surgery (approx. $20-30)
Nutrition		
Nutritionalist/Dietitian		
Alison Horton, RD, CLE	885-3731	
Organic Food Stores		
Good Life Grocery	282-9204	1524 20th St. (and Potrero)
Good Life Grocery	648-3221	448 Cortland
Rainbow Foods	863-0620	1745 Folsom Street, SF, CA
Real Foods	673-7420	2140 Polk Street, SF, CA (and Broadway)
Real Foods	567-6900	2169 Filbert Street, SF, CA (and Fillmore)
Real Foods	564-2800	1023 Stanyan Street, SF, CA (and Carl)
Real Foods	282-9500	3939 24th Street, SF, CA
Whole Foods	674-0500	1765 California Street, SF, CA (and Franklin)

Organic Food Home Delivery		
Farm Fresh to You	1-800-796-6009	
The Box	695-9688	
Planet Organic	522-0526	
Mother's Organics (Marin Only)	454-2071	
Cooks		
Gail Kennedy	408-749-8147	cooks in 5 hr shifts; brings in food and makes enough for 2-3 days
Mind Body Programs		
Bay Area Jewish Healing Center (SF)	750-4199	
Cancer Support and Education (Menlo Park)	(650) 327-6166	
Center for Attitudinal Healing (Sausalito)	331-6161	
Charlotte Maxwell Clinic (Oakland)	510-601-7660	
Commonweal (Bolinas)	868-0970	
Health and Healing Clinic (CPMC)	923-3503	
Institute for Health and Healing (CPMC)	202-1562	
Wellness Community (Walnut Creek)	510-933-0107	
Yoga/ Stress Reduction		
UCSF- Yoga	885-3693	2330 Post Street, Suite 510; Thursday 12:30-1:30pm
UCSF- T'ai Ch'i	885-3693	UCSF Cardiac Care Gym; led by Alyce Bridges; Wednesday 12-1pm
Dawn Summers at Valley Chiropractic	550-1200	1326 Church (25th and Clipper); classes and also individual sessions
Mindful Body	931-2639	2876 California (Broderick and Divisadero) gentle yoga and stretching
Inst. of Health and Healing- Yoga	561-1374	2300 California St., Suite 200, SF, CA; 10 week yoga course
Inst. of Health and Healing- Stress Reductio	202-1562	2300 California St., Suite 200, SF, CA; 8 week stress reduction course
Inst. of Health and Healing- T'ai Chi Ch'uan	202-1562	2300 California St., Suite 200, SF, CA; 12 week course
Inst. of Health and Healing- Qi Gong	202-1562	2300 California St., Suite 200, SF, CA; 6 week course
Integral Yoga Institute	821-1117	770 Dolores Street, SF, CA
Radha Vignola	408-427-3211	Santa Cruz
Janet Piggins	510-891-9560	Oakland
Jnani Chapman	332-2478	Sausalito

Art		
Art for Recovery	885-7221	Cindy Perlis
Dance/Movement		
General		
UCSF- Mobilizing Spirit	885-3693	Anne Kranz
Body Dynamics	753-3576	Diane Neighbor; classes and individuals
Body Tales	510-547-4467	Olivia Corson; Oakland
Gabrielle Roth's Work	388-0431	Mill Valley, CA
Structured Improvisation- Continuum	454-3451	Ann McGinnis
Structured Improvisation- Continuum	408-662-9055	Beth Pettengil Riley
Breema		
SF Breema Center; Self-Breema	621-2243	Evan Specter
Emeryville Clipper Club	501-601-5195	Eliane Wallis
Denise Berezonsky	255-7947	individual and small groups
Freestyle		
Knight Boogie (Freestyle)	453-6232	Christina; at Rhythm and Motion, 1133 Mission St. (btwn 7th and 8th)
Dance Jam	453-6232	Declan or Christina; Berkeley
N. CA. Dance Collective	453-6232	weekend and week long retreats
Authentic Movement		
Karne Korn-Hauser	510-597-0918	
Ellen Friedman	510-526-6729	
Sandy Dibbell-Hope	510-843-1396	
Massage Therapists		
Karen Korn-Hauser	510-597-0918	
Gyms/Exercise Physiologists		
Dynamic Balance	346-1691	
UCSF- Exercise Class for Cancer Patients	885-3693	

Lymphadema Education and Tmt		
Cheryl Perry, RN	650-780-6795	
Aurora Lymphadema Clinic	921-2911	2211 Post St, Suite 404, San Francisco; Saskia Thiadens, RN;treatment
National Lymphadema Network	1-800-541-3259	24 hour hotline for education and referral
Stanford Lymphadema Service	650-498-6921	
Aesthetic Services		
Look Good, Feel Better Workshop	885-3693	Free American Cancer Society Wksp to improve appearance during tmt.
Wigs		
Lady's Touch- SF and Marin	454-6058	Marin and San Francisco
Lady's Touch- East Bay	510-655-4547	East Bay
Studio International- SF	626-5583	15% discount card available at UCSF/Mt. Zion Cancer Resource Center
Face to Face-SF	566-2806	state tax waived with prescription
Wig Palace of San Mateo	(650) 347-6125	works strictly with cancer patients; offers insurance reimbursements
Breast Forms		
Lady's Touch	454-6058	Marin and San Francisco
Lady's Touch	510-655-4547	East Bay
Nordstrom's- Bay Area	408-261-5740	Deborah Jastilahn; Breast Form Coordinator
Breast Cancer Advocacy Grps		
The Breast Cancer Fund	543-2979	
Breast Cancer Action	243-9301	
Y-ME/Save Ourselves Breast Cancer Org.	916-448-5432	
Susan G. Komen Foundation	474-9377	
Other Bay Area Support Groups		
San Francisco		
Cancer Support Community (Jane Kraft)	388-3742	

Kaiser Hospital (Leslie Rose)	202-3759	
St. Mary's (Diane Scott)	750-5775	
Seton (Joan Evans)	991-6604	
	991-6604	
Marin/North Bay		
Marin General Hospital (Circle Center)	925-7920	
Kaiser Santa Rosa (Beth Arvidson)	571-4698	non-Kaiser patients welcome
Recurring or Metastatic Breast Cancer	383-5983	Carol Kronenwetter; Greenbrae
Bosom Buddies (Robin Richard)	707-996-3891	Sonoma
East Bay		
Alta Bates (Shirley McKenzie)	510-204-4330	
Women's Cancer Resource Center	510-548-9272	
	510-548-9272	
Palo Alto		
Community Breast Health Project	(650) 725-1788	
Specific Support Groups		
African American	510-548-9272	
Asian (CSC)	788-2131	
Bereavement (UCSF; Debra Marks, PhD)	885-7415	
Bereavement (Anna O'Brien)	626-5900	
Children/Family Sessions (UCSF)	885-7415	
Children and Families	202-1562	
Children Whose Parents Have Cancer (CSC)	648-9400	
Couples (UCSF; Debra Marks, PhD)	885-7415	
DCIS (Debbie Marks; now forming)	885-7415	
Family and Friends (CSC)	648-9400	
Kids Helping Kids	327-6166	
Latinas (CSC; Carmen Ortiz)	648-9426	
Lesbians (Women's Cancer Resource)	510-548-9272	
Lesbians (Lyon-Martin)	565-7672 X370	
Lymphedema (Aurora Lymph Clinic)	921-2911	

Metastatic Breast Cancer (Marin)	925-7920	
Metastatic Cancer (CSC; San Francisco)	648-9400	
Partners (East Bay)	510-204-1591	
Partners (Bill Bowersock)	457-0378	
Russian (Raya Smail; now forming)	885-7415	
Spirituality & Breast CA (Laurie Garrett)	563-4321 X72841	
Spirituality & Metastatic CA (Garrett)	563-4321 X72841	
Women Under 40 (Susan Shavin)	510-204-1769	

Carrie Sanders & Laurel Bray-Hanin
Present

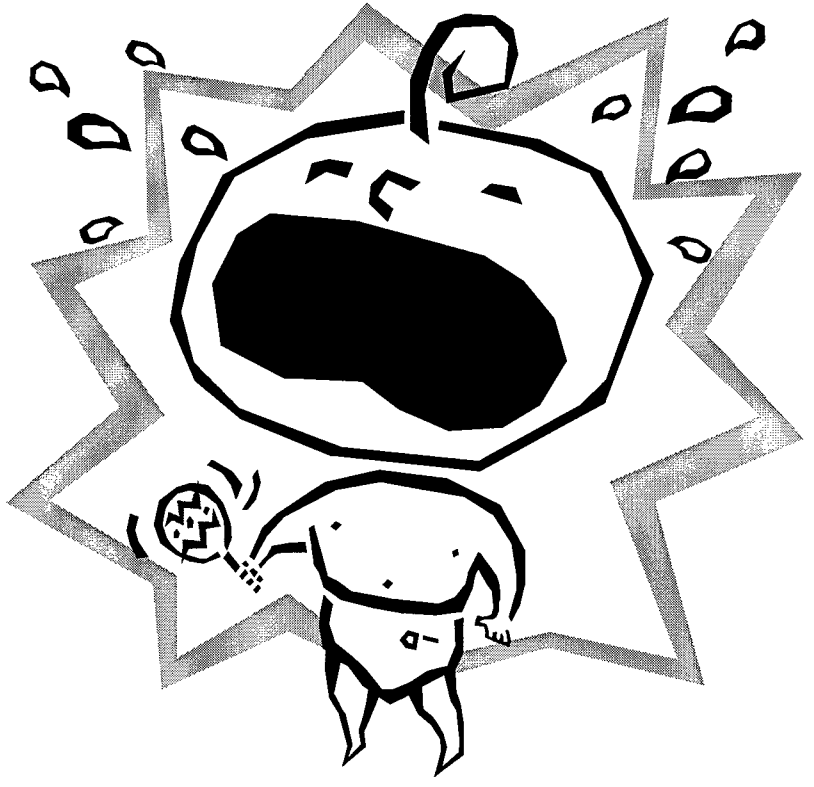
Follow-Up Program Development and Implementation Plan at the Breast Care Center

UCSF Cancer Center

Introduction

- Vision of the BCC
  - Brief history
  - Comprehensive Breast Care Center
  - Multidisciplinary Team Approach
- Why we are taking this class

Why we chose this project?

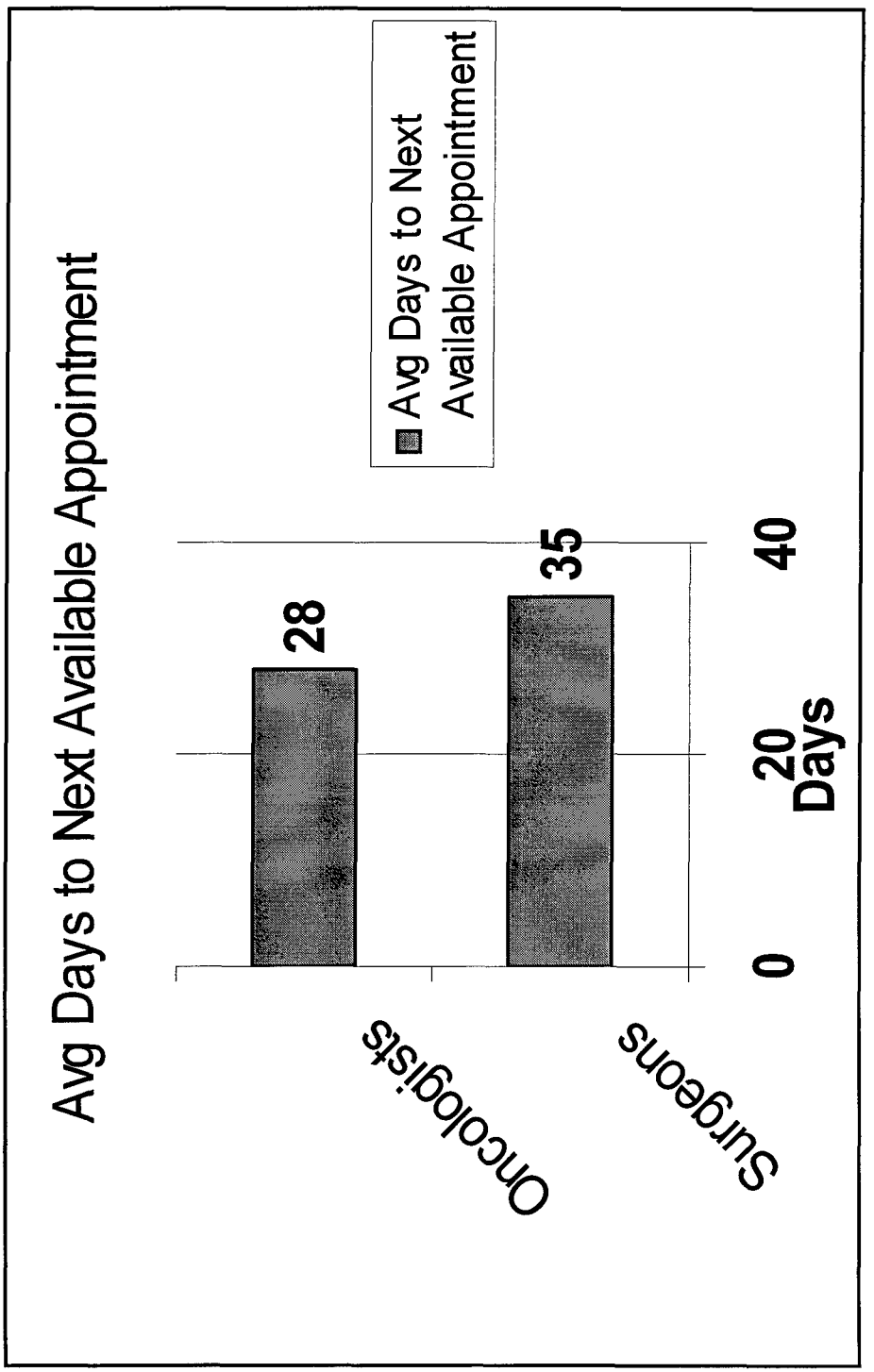


- Patient dissatisfaction
  - No availability
  - Office delays
  - Excessive number of follow-up visits per patient
- No data
- Variation in standards of care
- Physician dissatisfaction
  - Overbooked schedules
  - Commitment to seeing new cancer patients but no available appointments
- Rapid growth of center lacking infrastructure to sustain itself.
- To make room in the schedule for a surgical same day diagnostic program

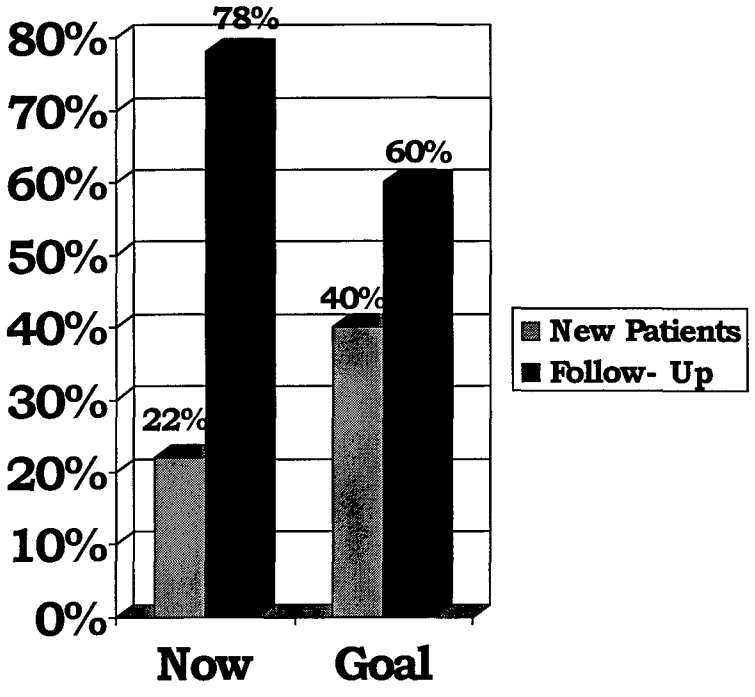
Project Objectives

- Standardize / Reduce Variability
- Create Available New Patient Appointments
- Collect Data
- Improve Efficiency
- Encourage Cost Effectiveness
- Promote Patient Centered Services
- Improve patient outcomes

When is the next available appointment?



What is the current break down of patient visits and what is our goal?



- Average patients seen per month is 440 (July 97-April 98)
- Currently 97 patient visits per month are new and 343 are follow-up patient visits.
- The Goal is to see 40% new patient visits and 60% follow-up patient visits per month.

Follow-Up Program Now & Future

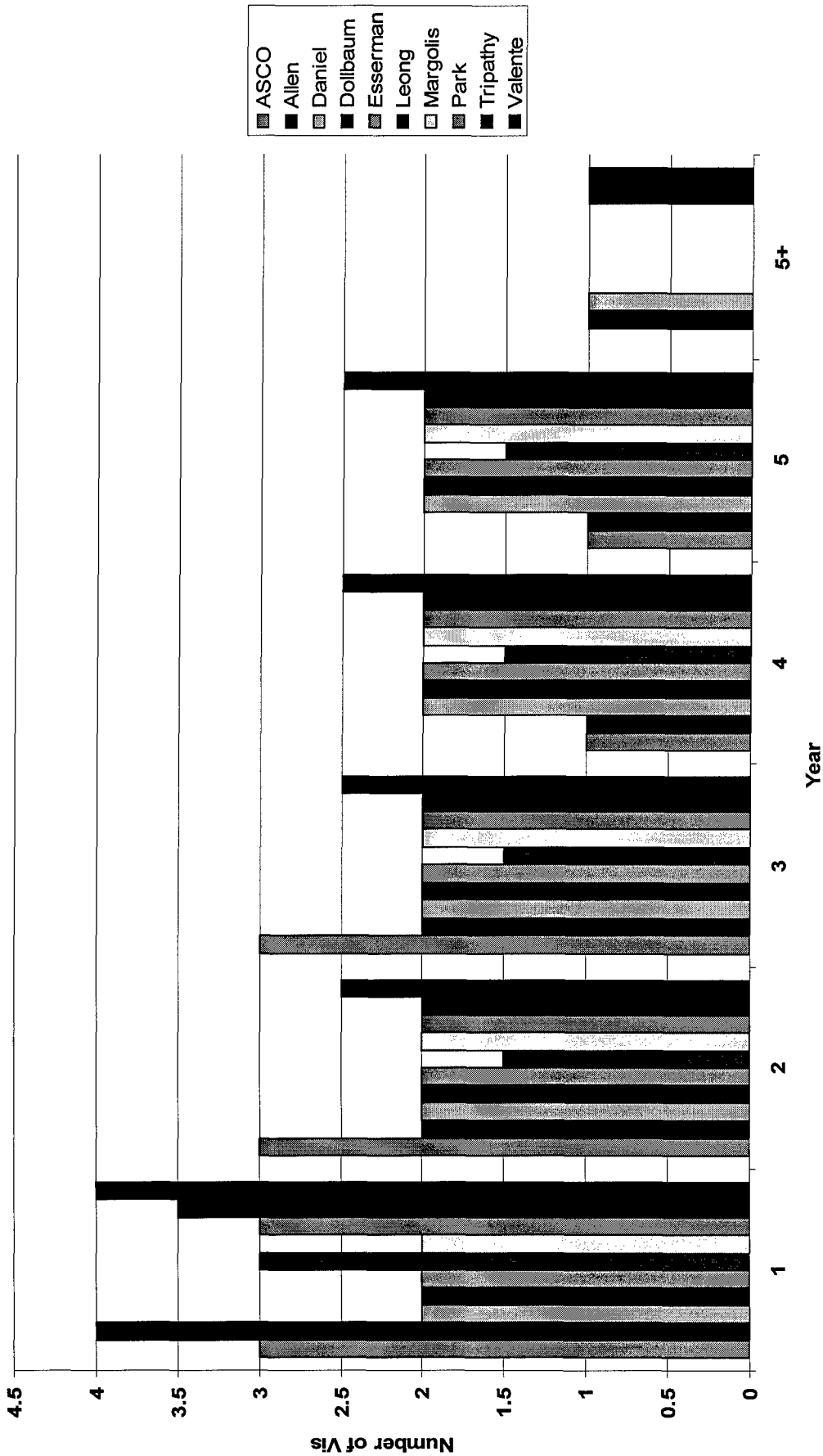
Now

- No "Program"
- Currently patients are seen an average of 7 times per year for five years, not including visits for mammograms, lab work, etc.
- No standardized methodology for conducting diagnostic and screening tests.
- Very little continuing education among the specialists as a group.
- Patient's generally unaware of where they fit into the follow-up system and the big picture.

Future

- Multi-tiered Model
  - Stage of primary disease
  - Therapy regimen
- Reduce the overall number of follow-up appointments to 3 or less per year.
- Standardized clinical pathways
- Continuing education among specialists, learning from each other.
- Include the patient in their follow-up program, providing written plan.
- Group education sessions addressing commonly asked questions and concerns.

How many follow-up visits does a provider average each year compared to ASCO?



What are typical post surgical mammogram regimens?

- Breast Conserving Therapy:
  - ASCO: Screening @6 months after completion of radiotherapy; then annually or as indicated for surveillance of abnormalities. If stability of mammographic findings is achieved, mammography can be performed yearly thereafter.
  - UCSF: 7 of 9 physicians do a diagnostic mammogram every 6 months for five years on the breast that had cancer and an annual screening mammogram on the other breast. 1 of 9 does a bi-lateral screening mammogram annually. 1 of 9 does a screening mammogram every 6 months for 2 years and then annually on the breast that had cancer.
- Non-Breast Conserving Therapy:
  - ASCO: Unilateral screening mammogram annually.
  - UCSF: 9 of 9 do a unilateral screening mammogram annually.

Why we want to collect outcome data:

- Patient questions
- Marketing tool
- To Improve patient outcomes
- Influence the MDs to improve their skills
- Find areas where we need more training, programs and education

What outcome data do we want to collect?

- **Service outcomes we want to collect**
  - Patient satisfaction
  - Provider satisfaction
  - Wait time for an appt.
  - Ratio of new patient appointments to f/up
  - Referring MD satisfaction
  - Staff satisfaction

- **Medical outcomes we want to collect:**
  - Lymphedema rates
  - Complication rates
  - Pain
  - Recurrence rates
    - local vs. distant
  - Average time from tx to resuming pre-treatment activity
  - Adverse events
  - Other cancers
  - Sensation
  - Mobility
  - Satisfaction
    - Overall
    - Cosmetic
  - Hematomas

What does the Literature suggest?

- Loprinzi, C. It is Now the Age to Define the Appropriate Follow-Up of Primary Breast Cancer Patients. *J. Clinical Oncology*. 1994;12:881-883
- GIVIO Investigators. Impact of Follow-Up Testing on Survival and Health-Related Quality of Life in Breast Cancer Patients. *JAMA*. 1994; 271: 1587-1592
- DelTurco, et.al. Intensive Diagnostic Follow-Up After Treatment of Primary Breast Cancer. *JAMA*. 1994; 271: 1593-1596

Other Follow-Up Program Models

Memorial Sloan Kettering:

- See a MD 3x a year / quarterly
- Standard is to see each specialist 1x a year (surgeon, medical oncologist, radiation oncologist)
- If they don't need one of the three specialist, then the medical oncologist fills in.
- Oftentimes patients who have had adjuvant therapy have complicated side effects and issues which continue on past their active therapy. These patients are seen 3x per year by the Medical Oncologist only.

UCLA:

- Team consists of:
  - Nurse Practitioner
  - Nutritionist
  - Social Worker
  - Physical Therapist
- DCIS
  - See the Team every 6 months x 2 years then annually x 3 years
- Stage I
  - See the Team every 3 months x 2 years, then every 6 months x 3 years.
- Stage II-III
  - See the Team every 3 months x 2 years, then every 6 months x 3 years, alternating with a Medical Oncologist.

How did the doctors rank the different follow-up scenarios?

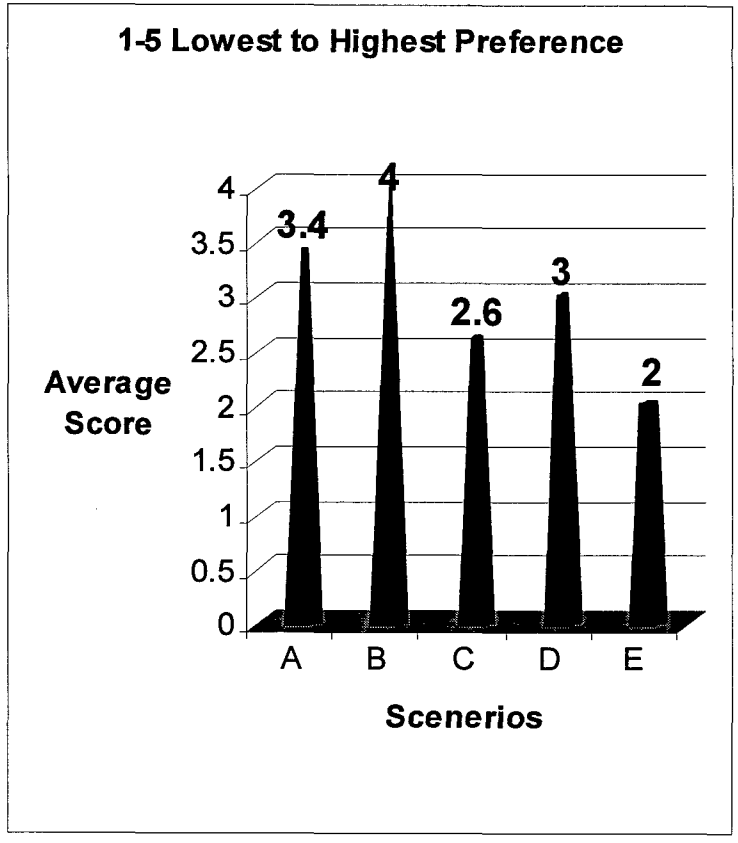
A One specialist provides <u>all</u> follow-up appointments.

B Leapfrog visits with other specialists.

C Advanced Practice nurse provides follow-up care. If abnormalities discovered, MD brought into care immediately.

D Leapfrog visits between Advanced Practice nurse & one specialist.

E They way it is now, each patient sees each specialist per their prescribed unique regimen.



How will we measure the impact?

Quality Objectives	*Measurement Tools*	*Measurement Intervals*
Patient Satisfaction	Surveys	At each f/up visit
Provider Satisfaction	Surveys and Interviews	Every three months
Wait time for an appt within 1 week	Track availability and chart	Twice/month (1st and 15th of the month)
Wait time in waiting room < 20 minutes	Track and chart	Track times once every two weeks per doctor
Reduce the number of total routine f/up visits each patient has	Chart or appt. schedule review	Quarterly
Increase the new patient volume to 40% total patient visits	Monthly volume statistical reports	Monthly
Referring Physician Satisfaction	Survey / Focus Groups	Bi-Annually
Medical Care Outcomes (Lymphedema Rate,e tc.)	Informatics system scanning patient information from exam forms	Daily

Next Steps.....

- Collect baseline satisfaction data for patients, physicians, and referring physicians.
- Develop and Implement standardized protocols, including exam form.
- Measure impact of program.

BAY AREA BREAST CANCER FORUM MINUTES
WEDNESDAY, MAY 6, 1998

"What is Quality Care?: A Patient's Perspective"

Dr. Laura J. Esserman began the discussion by stating that she felt the place to start analyzing quality of care is with the patient who has been through the process. She expressed hope that the meeting would yield much information which would have far reaching consequences for making the Breast Care Center a more efficient, more compassionate environment for people with cancer.

Meryl Brod, PhD. made the point that patients may have different goals or perceptions of quality than the physician does. She basically wants the answer to two questions:

1. What makes care "good"?
2. What did you want as a patient that you didn't get?

We will go through all the phases of diagnosis, treatment, and follow up in order to get answers to these questions.

Diagnosis:

First step in diagnosis is the **mammogram**. Most of the audience agreed that quality care at this stage would involve a gentle, considerate technician who is well trained. Most people would like to have their mammogram read right away so that they don't have an agonizing wait for results. When the technician says that everything is okay, does that mean the quality of the film or the result of the exam?

Many women did not know the difference between a screening mammogram which is done as a routine part of a yearly exam, and a diagnostic mammogram which is done in response to some problem found, like pain or a lump. They would like to have a radiologist present to read the films and give them a result before they leave. They would like this for all scans. This way you can eliminate a great deal of the anxiety caused by false positive tests, and also be able to get a follow-up film immediately. Most women also felt the need for a **compassionate companion,** this could be a technician or knowledgeable staff person. Dr. Esserman pointed out that although mammography is effective, greater that 70%, it is not perfect and does not eliminate the anquish of a false negative test.

Recalls should be handled compassionately, honestly, and in a time sensitive manner, not by mail. The recaller should have **information** about your case, and call you promptly. No one wants to wait for weeks to find out whether or not they have a problem.

Biopsy:

Any way waiting time can be shrunk is helpful; immediate biospy should be an option. Coping strategies about how to get through the waiting time did not seem as important as **compassion** from the physician throughout the process. Continuity of care is important as is more **information** about treatment options and the process, perhaps in booklet form. Knowing the diagnosis with enough time to evaluate treatment options is important; i.e. shorten the time interval to diagnosis, but **lengthen** the time interval from diagnosis to treatment. **Accurate** information should be provided as a standard part of the appointment, perhaps in the form of videotapes which patients can watch while waiting, or beepers might be provided so that patients could access the Resource Center while waiting. In addition, it is equally important that the patient's emotional and psychological needs be met, so a **human being** available at all times means more than anything.

At The Time Of Initial Diagnosis:

Most people would prefer to receive the diagnosis in person, some would prefer over the phone if it's sooner; but all would like the **option** as to how to be told given to them at the time of the biopsy.

It is optimal, when you have to see multiple physicians, to have them all in one place. A case manager who could organize your choices would be good--one stop shopping.

In a **perfect world**, one would like: help navigating insurance, a 24-hour hotline staffed by a physician, a treatment plan, glossary of oncology terms, ability to tape record meetings with the physician.

Surgery (lumpectomy):

Very important that the patient knows who is doing the procedure, surgical or anesthesia. In a teaching hospital, do we have the option of not having a physician-in-training? Patient would want to know the **experience** of the surgeon.

Information on what to expect after the procedure is finished, downstream consequences of your choice of lumpectomy. Anything which would minimize worry and confusion would be helpful: convenience of parking and making appointments, tours of the facilities, videos on different procedures, support information for spouse/partner, checklist of important questions to ask, etc.

Mastectomy:

After this procedure, patients need more information and preparation for what to expect. Navigators would have a place in this system as well. The medical profession needs to understand that this is new territory for most women, and needs to provide more attention to **small details** that may be overwhelming for the patient. Attention to childcare issues: how to talk about cancer at different ages, support for people alone or for the rest of the family. Deal with the person--not just the patient.

Chemotherapy:

- **Information** on expectations, process, and options is needed.
- Patients would like to discuss which agent is best, and get second opinions.
- Getting information on the Internet at the Resource Center, checking on your own results on your own webpage, where people would have access to their records, and have the ability to copy notes.
- Make the waiting more bearable by watching movies or listening to music.
- **Information** on nutrition, health, exercise, alternative treatments, clinical trials and ongoing research would be valued.

Radiation:

Patients do not want to wait in the waiting room for their appointments. Privacy is an issue. Patients want more **information and preparation** at the first appointment. (What is: set up, tatoo, simulation) A single sheet summary would be good.

In general patients want **client satisfaction** (like they get in a hotel), this would include feedback on their cases, information on the health professionals that treat them, a sort of report card on the treatment center.

Follow-Up Appointments:

The goal of the Center is to see patients in a timely manner, but still answer all the patient's questions. Need to find out the kinds of things that people want: counselling for nutrition and exercise, etc., and then develop a program which will fit within the time constraints of the Center. Patients would know how long the appointment is so that they can prioritize their questions.

A new model that is proving to be very successful for follow up appointments provides a **group session** for half an hour and then small private sessions. The patients seem to get a lot

more information, in part because they benefit from the questions and experiences of other patients. Nurse practitioners would be used for what they do best, and the doctors time is utilized more efficiently.

Patients feel like they need to be "on their toes" all the time. They would like to have an **advocate** who would take on some of this responsibility, especially for groups like the elderly. Someone who would call after the first chemotherapy treatment to make sure the patient is okay, or check in with the patient the day after a procedure, or just to get answers to "niggling" little questions they do not want to bother the physician, nurse practitioner, or office with.

Next meeting: Wednesday, June 10. 1998, topic will be Alternate and Complementary Therapy.

Front Staff Questionnaire

Name:_____ Date:_____

Name of MD/Nurse:_____

Please fill out the following questionnaire and circle the appropriate response.

1. When the doctor /nurse asks me to do something for him/her, they asked me in a nice respectful manner.

Strongly agree Agree Disagree Strongly disagree

2. When the doctor/nurse asks me to do something for him/her, they let me know how to prioritize their request.

Strongly agree Agree Disagree Strongly disagree

3. When I bring a problem to the doctor/nurse's attention, the physician helps me to solve the problem w/o putting the blame on me or making me feel stupid.

Strongly agree Agree Disagree Strongly disagree

4. When I need to ask the doctor/nurse a questions he/ she gives me their undivided attention.

Strongly agree Agree Disagree Strongly disagree

5. I feel comfortable asking the physicians/nurses a question.

Strongly agree Agree Disagree Strongly disagree

6. When I leave notes from patients for the physician/nurse, they take care of these matters before the patient has a chance to call again because the matter wasn't taken care of.

Strongly agree Agree Disagree Strongly disagree

7. The physician's/nurse's patients did not complain about having to wait to be seen.

Strongly agree Agree Disagree Strongly disagree

8. When I ask the physician/nurse to do something, they followed through with the task.

Strongly agree Agree Disagree Strongly disagree

9. When a problem in their schedule came up, the MD/nurse helped me to solve the problem and figure out what happened.

Strongly agree Agree Disagree Strongly disagree

10. I feel that what the MD/nurse asks of me is reasonable and fair.

Strongly agree Agree Disagree Strongly disagree

11. The physician/nurse treats me as part of the BCC team.

Strongly agree Agree Disagree Strongly disagree

12. I feel appreciated by the physician/nurse.

Strongly agree Agree Disagree Strongly disagree

Other comments:_____

_____

_____

_____

_____

When you are finished please put these in Carrie's box in the manilla folder labled questionnaires. Thank you.

MD/Nurse Evaluation Form

Your name:_____ Date:_____

Please fill out the following questionnaire and circle the appropriate response.

1. My charts are complete and are prepared on time.

Strongly agree Agree Disagree Strongly disagree

2. When I ask a front office staff member to take care of something I feel that they listen and follow through as needed.

Strongly agree Agree Disagree Strongly disagree

2a.When I ask a back office staff member to take care of something I feel that they listen and follow through as needed.

Strongly agree Agree Disagree Strongly disagree

3. I feel that when a mistake occurs, the fd person helps me to solve the problem.

Strongly agree Agree Disagree Strongly disagree

4. I feel that when I need help there is someone there to help me.

Strongly agree Agree Disagree Strongly disagree

5. I get positive comments from the patients about the front office staff.

Strongly agree Agree Disagree Strongly disagree

6. When I call the BCC I am greeted appropriately on the phone.

Strongly agree Agree Disagree Strongly disagree

7. The fd staff does not schedule patients during times that blocked off for other engagements.

Strongly agree Agree Disagree Strongly disagree

8. I feel appreciated by the front office staff.

Strongly agree Agree Disagree Strongly disagree

9. I feel appreciated by the other medical providers at the BCC.

Strongly agree Agree Disagree Strongly disagree

10. Current reports(lab, radiology, etc) are in the chart prior to the chart being given to me.

Strongly agree Agree Disagree Strongly disagree

11. Phone calls are screened and taken care of appropriately.

Strongly agree Agree Disagree Strongly disagree

Other comments:_____

_____

_____

_____

_____

When you are finished please put these in Carrie's box in the manilla folder labled questionnaires. Thank you.

Continous Quality Improvment Study

UCSF Breast Care Center
Radiology, Surgery, Pathology

Richard Lin, MD

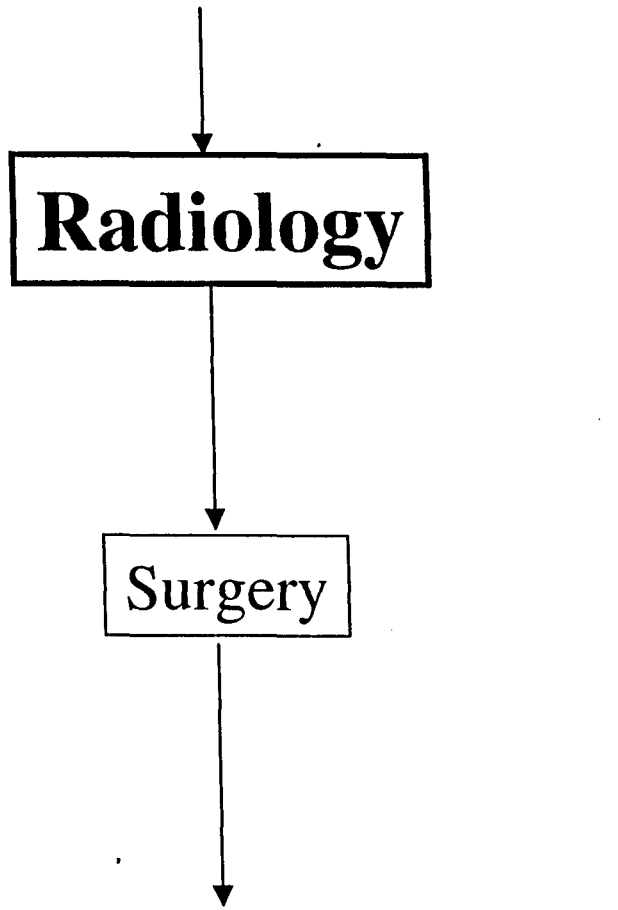
Purpose of Investigation

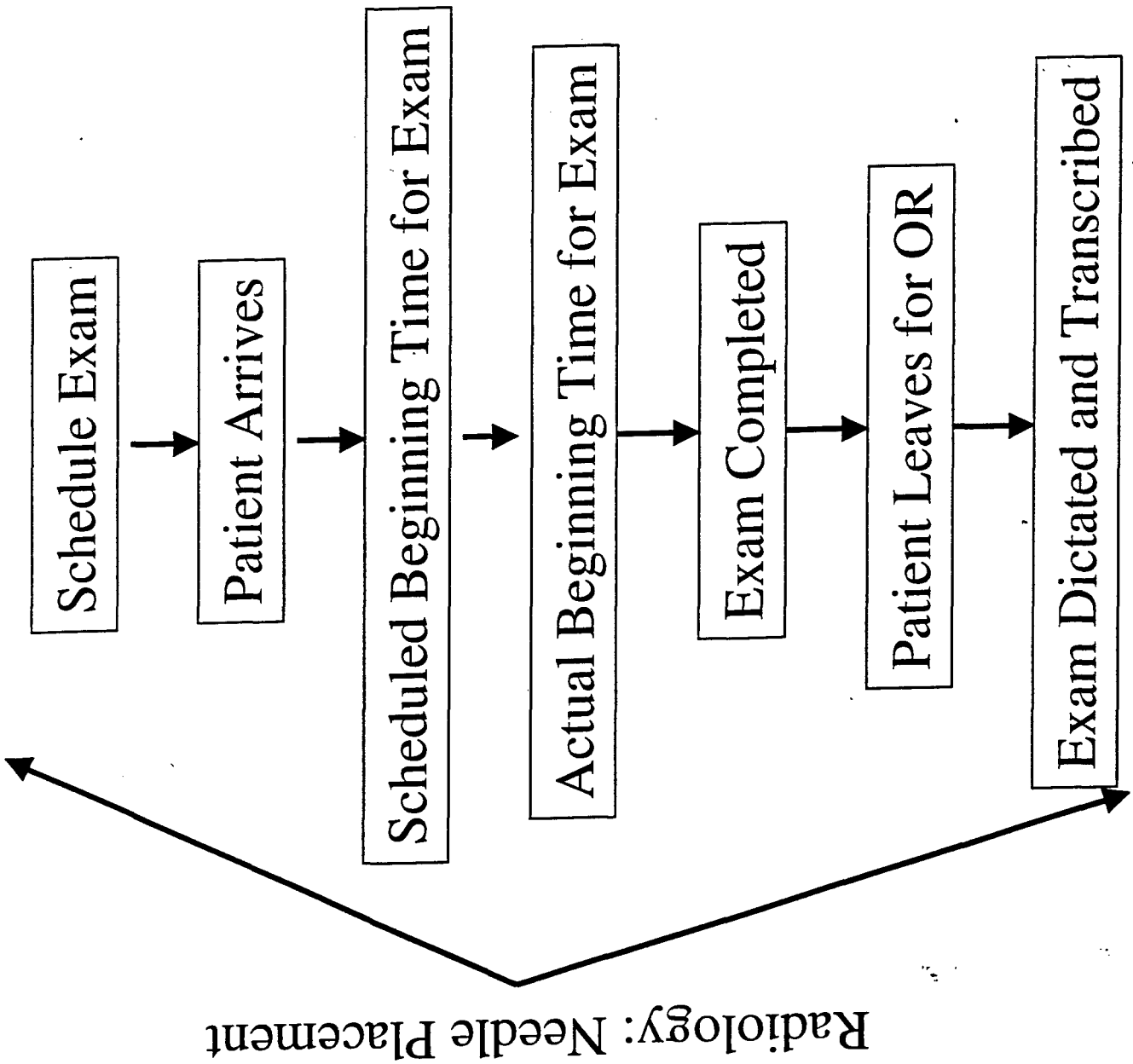
- Identify degree of variation in procedure times for different stages
- Identify correlations between variables and time as a quality measure
- Formulate hypotheses on potential special causes
- (Post-study) Test hypotheses and formulate solutions to reduse statistically significant variation ("special causes") and average time (best practices)

Current System: Quality Issues

- Procedure Time
  - Variation in time
  - Length in time
- Pathology process time
  - Accuracy
  - Variation and length in time

Time Variation Analysis by Department




Radiology: Needle Placement
Schedule Exam
Patient Arrives
Scheduled Beginning Time for Exam
Actual Beginning Time for Exam
Exam Completed
Patient Leaves for OR
Exam Dictated and Transcribed

Radiology Data

- Collected time data since July 1989
- Over 1300 cases

Time Data

- When scheduled
- Patient arrival
- Scheduled begin
- Actual begin exam
- Complete exam
- Transcribed exam findings

Possible Independent Variables

- Institution - two sites
- Year
- Age of patient
- Radiologist
- Presence of second radiologist
- Referring surgeon
- Referring department/institution

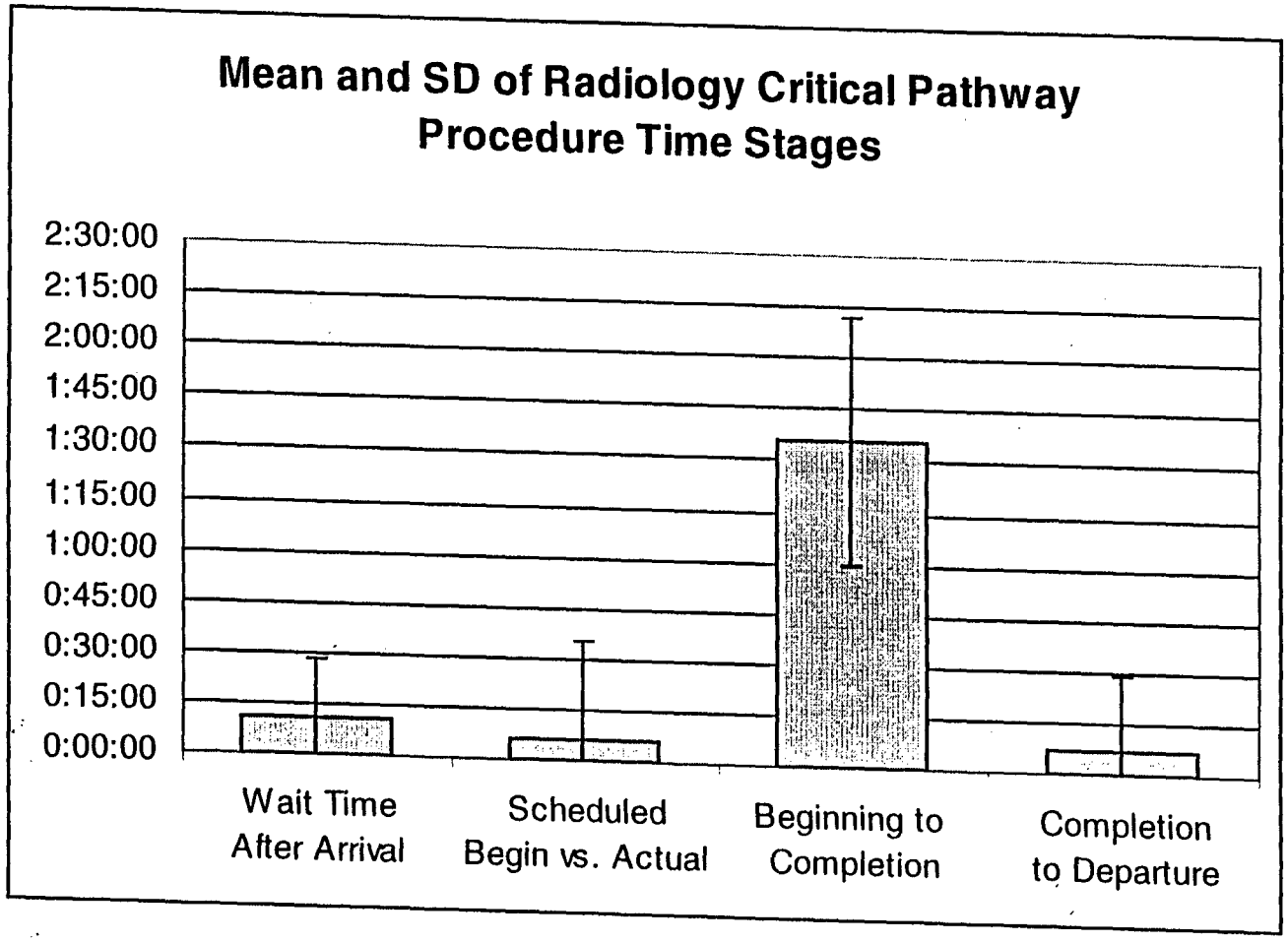
Parameters of Quality Analysis

- Focus on radiology time stages
  - Five critical pathway time stages:
    - Days waited for an appointment
    - Waiting time after patient arrival
    - Schedule vs. actual exam begin time
    - Beginning to completion of procedure
    - Completion to patient departure
  - One non-critical time stage: Completion of procedure to dictation of results

Variation in Procedure Times

	Wait Time for Appointment	Wait Time After Arrival	Scheduled Begin vs. Actual	Beginning to Completion	Completion to Departure	Completion to Dictation
	(in days)	(in hours)				
MEAN	9.73	0:10:55	0:06:08	1:35:59	0:07:04	10:45:44
STDEV	7.50	0:17:40	0:29:04	0:36:06	0:21:51	8:34:02

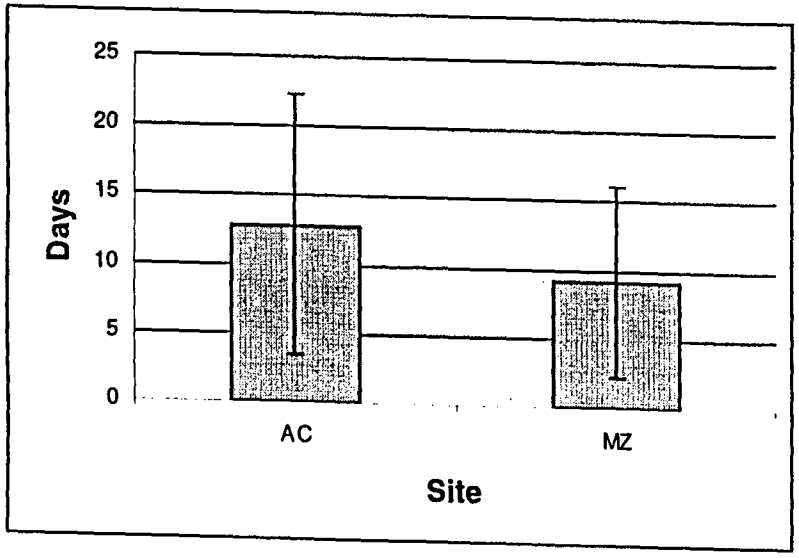
Variation in Procedure Times
(cont'd)



Days Waited for Appointment

- Mean: 9.73 days
- Standard deviation: 7.50 days
- Key independent variables
  - Procedure site
  - Referring physician

Days Waited - Procedure Site



	AC	*MZ*
Mean	12.9	9.1
Variance	89.3	47.9
Observations	92	486
Hypothesized Mean Difference	0	
df	110	
t Stat	3.613966753	
P(T<=t) one-tail	0.000228146	
t Critical one-tail	1.658822839	
P(T<=t) two-tail	0.000456292	
t Critical two-tail	1.981766218	

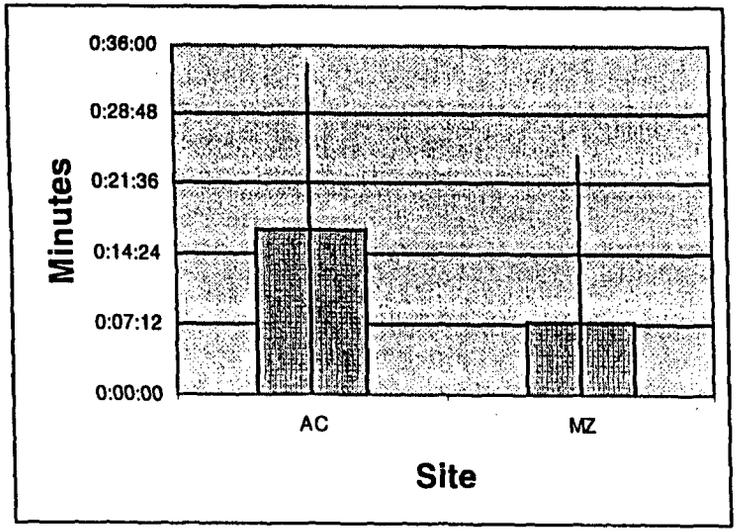
*Units in days; only non-negative values

* AC had a statistically more significant longer wait than MZ

Waiting Time After Arrival

- Mean: 10 min. 55 sec.
- Standard deviation: 17 min. 40 sec.
- Key independent variables:
  - Procedure site

Wait Time After Arrival - by Site



	AC	*MZ*
Mean	0.011644	0.005107
Variance	0.000140	0.000141
Observations	254	418
Hypothesized Mean Difference	0	
df	535	
t Stat	6.9337968	
P(T<=t) one-tail	5.925E-12	
t Critical one-tail	1.6477065	
P(T<=t) two-tail	1.185E-11	
t Critical two-tail	1.9644085	

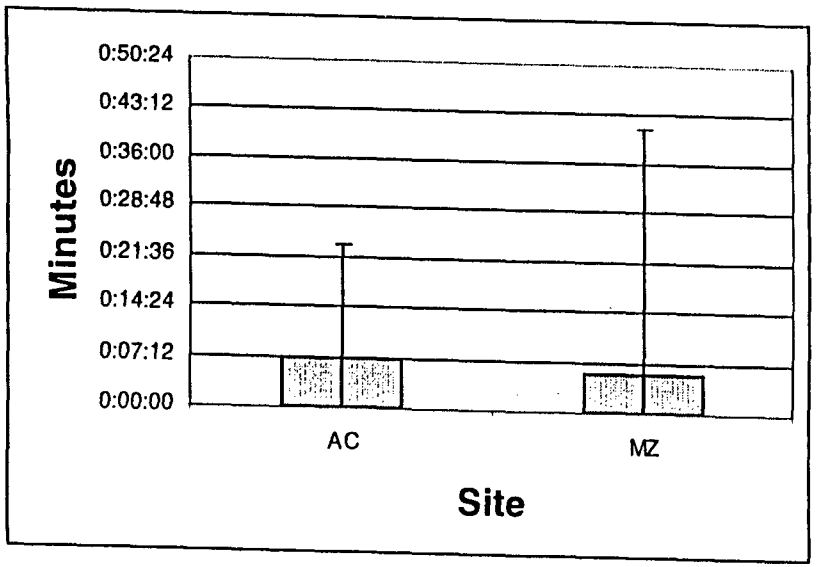
*Units in days; only non-negative values

* AC has statistically significant longer waiting time than MZ

Scheduled vs. Actual Begin

- Mean: 6 min. 8 sec.
- Standard deviation: 29 min. 04 sec.
- Key independent variables:
  - Procedure site
  - Radiologist

Schedule vs. Actual Begin - by Site



	AC	*MZ*
Mean	0.004823	0.003842
Variance	0.000131	0.000614
Observations	387	518
Hypothesized Mean Difference	0	
df	770	
t Stat	0.794874665	
P(T<=t) one-tail	0.213465672	
t Critical one-tail	1.646835699	
P(T<=t) two-tail	0.426931345	
t Critical two-tail	1.963048817	

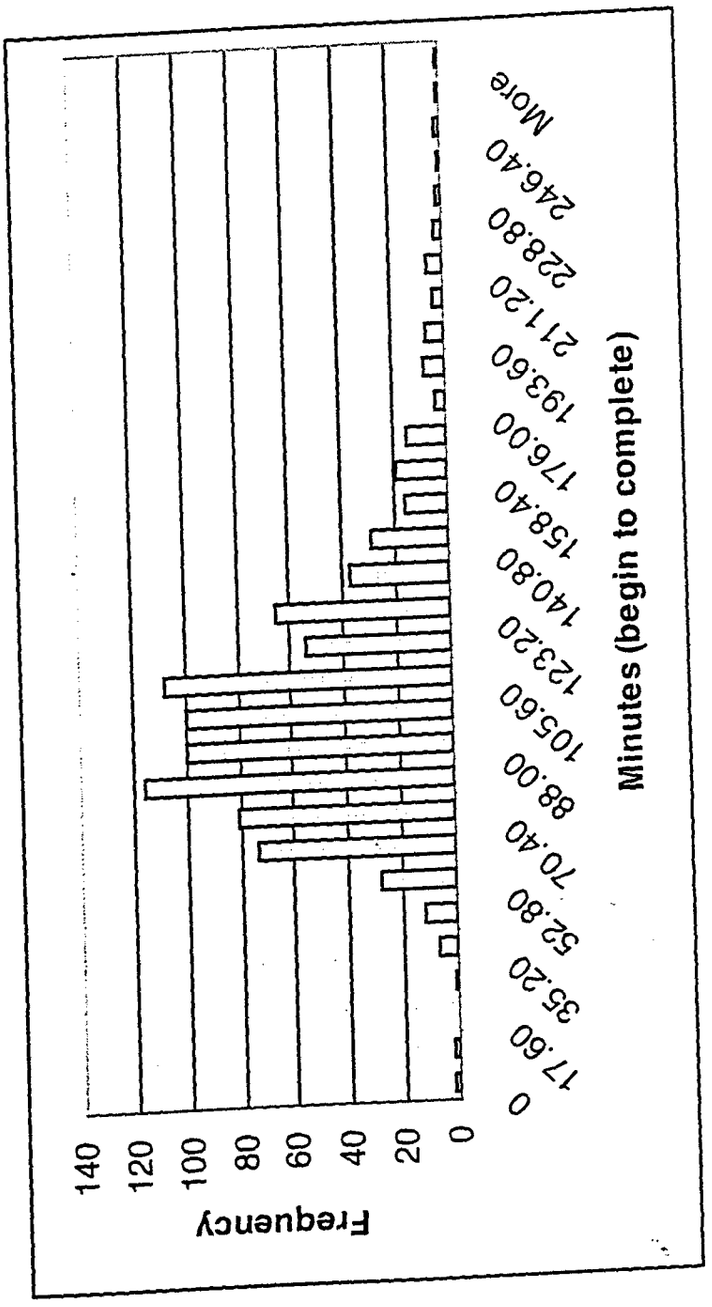
*Units in days.

* No statistically significant difference was found between sites

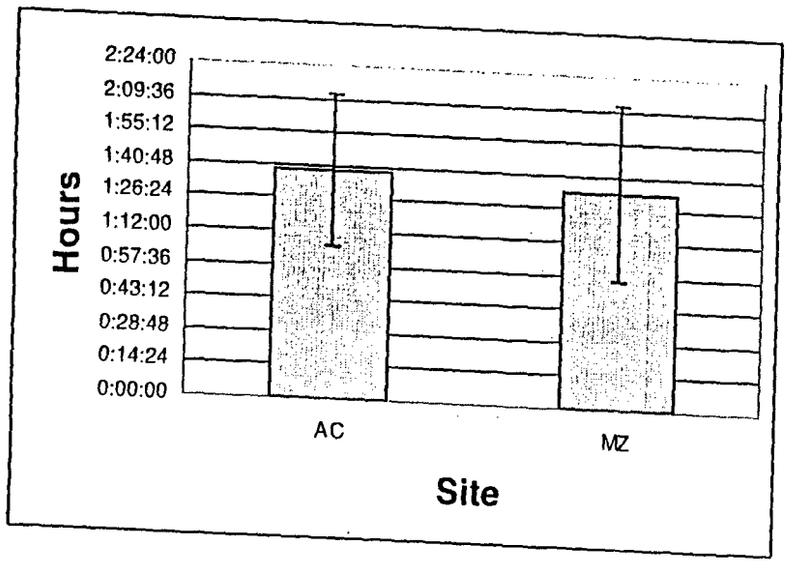
Beginning to Completion

- Mean: 1 hour 35 min. 59 sec.
- Standard deviation: 36 min. 6 sec.
- Key independent variables:
  - Procedure site
  - Referring institution
  - Radiologist
  - Age of Patient

Beginning to Completion - Data Distribution



Beginning to Completion - by Site

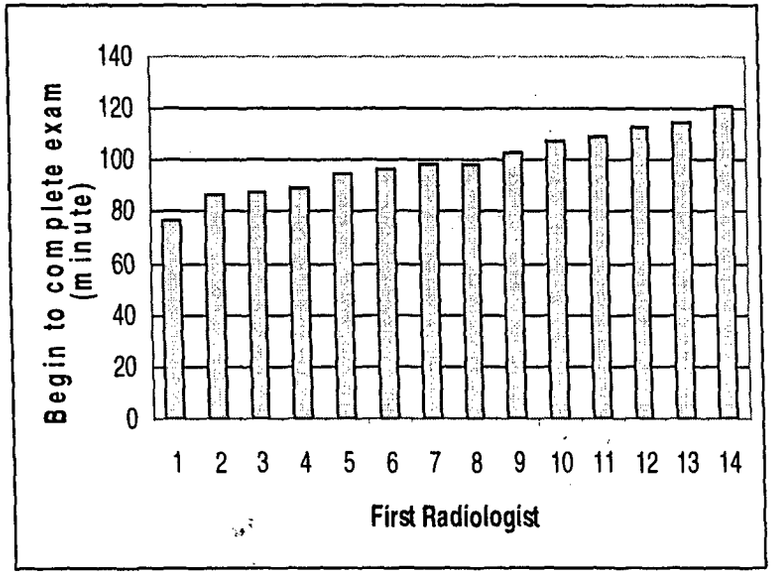


	AC	MZ
Mean	0.068551	0.065231
Variance	0.000525	0.000702
Observations	387	518
Hypothesized Mean Difference	0	
df	884	
t Stat	2.015551107	
P(T<=t) one-tail	0.022074561	
t Critical one-tail	1.646578767	
P(T<=t) two-tail	0.044149122	
t Critical two-tail	1.962653187	

*Units in days.

*AC has statistically significant longer procedure times.

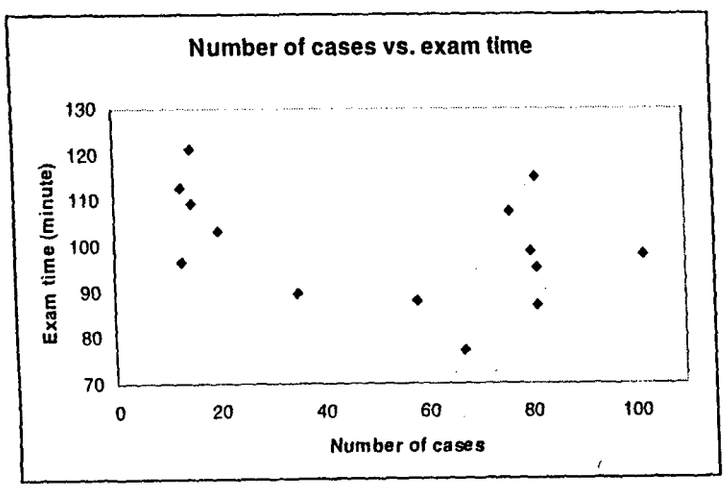
Beginning to Completion - by Radiologist



Best vs. worst radiologist
t-Test: Two-Sample Assuming Unequal Variances

	Variable 1	*Variable 2*
Mean	0.053586236	0.084212967
Variance	0.000237657	0.001629429
Observations	67	15
Hypothesized Mean Difference	0	
df	15	
t Stat	-2.891686595	
P(T<=t) one-tail	0.005590785	
t Critical one-tail	1.753051038	
P(T<=t) two-tail	0.01118157	
t Critical two-tail	2.131450856	

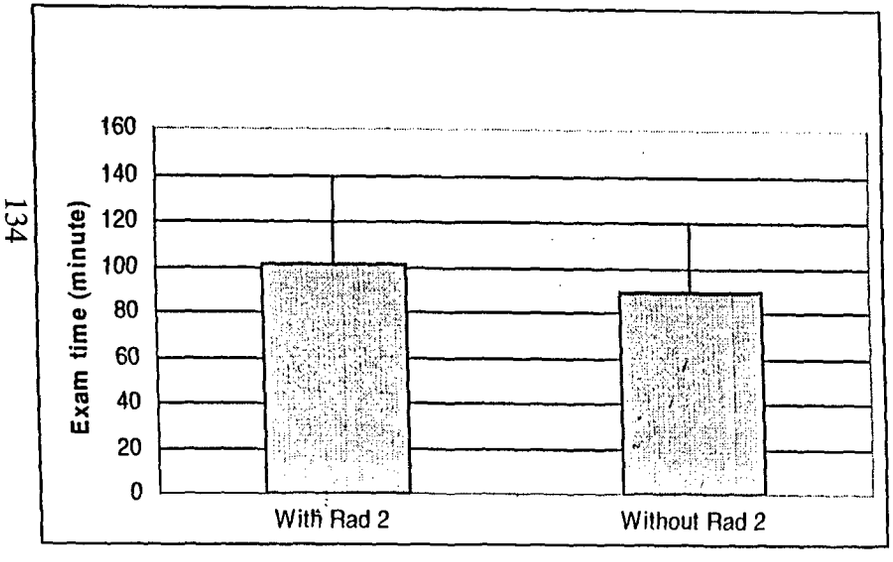
Experience vs. ExamTime



Regression Statistics	
Multiple R	0.35914778
R Square	0.128987128
Adjusted R Square	0.056402722
Standard Error	12.0291974
Observations	14

	Coefficients	Standard Error	t Stat	P-value
Intercept	107.1421693	6.288075218	17.03894523	8.97574E-10
X Variable 1	-0.136846502	0.10265549	-1.333065603	0.207266254

Beginning to Completion - With or Without a 2nd Radiologist

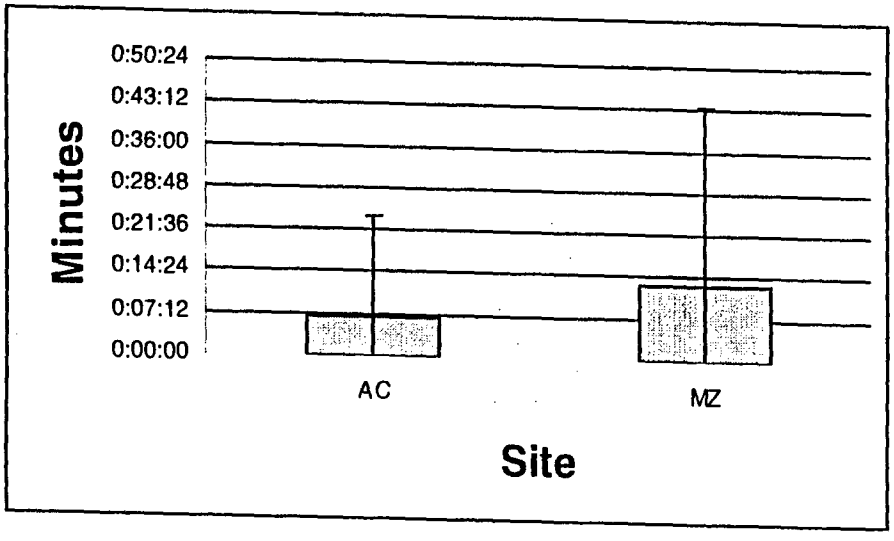


	Variable 1	*Variable 2*
Mean	100.9923664	89.54881267
Standard Deviation	38.4742463	30.7287952
Observations	524	379
Hypothesized Mean Difference	0	
df	892	
t Stat	4.96309565	
P(T<=t) one-tail	4.15469E-07	
t Critical one-tail	1.646562851	
P(T<=t) two-tail	8.30939E-07	
t Critical two-tail	1.962625902	

Completion to Departure

- Mean: 7 min. 4 sec.
- Standard deviation: 21 min. 51 sec.
- Key independent variables:
  - Procedure site
  - Radiologist

Completion to Departure - by Site



	AC	MZ
Mean	0.004712	0.009033
Variance	0.000140	0.000451
Observations	214	278
Hypothesized Mean Difference	0	
df	451	
t Stat	-2.8617578	
P(T<=t) one-tail	0.0022045	
t Critical one-tail	1.6482386	
P(T<=t) two-tail	0.004409	
t Critical two-tail	1.9652362	

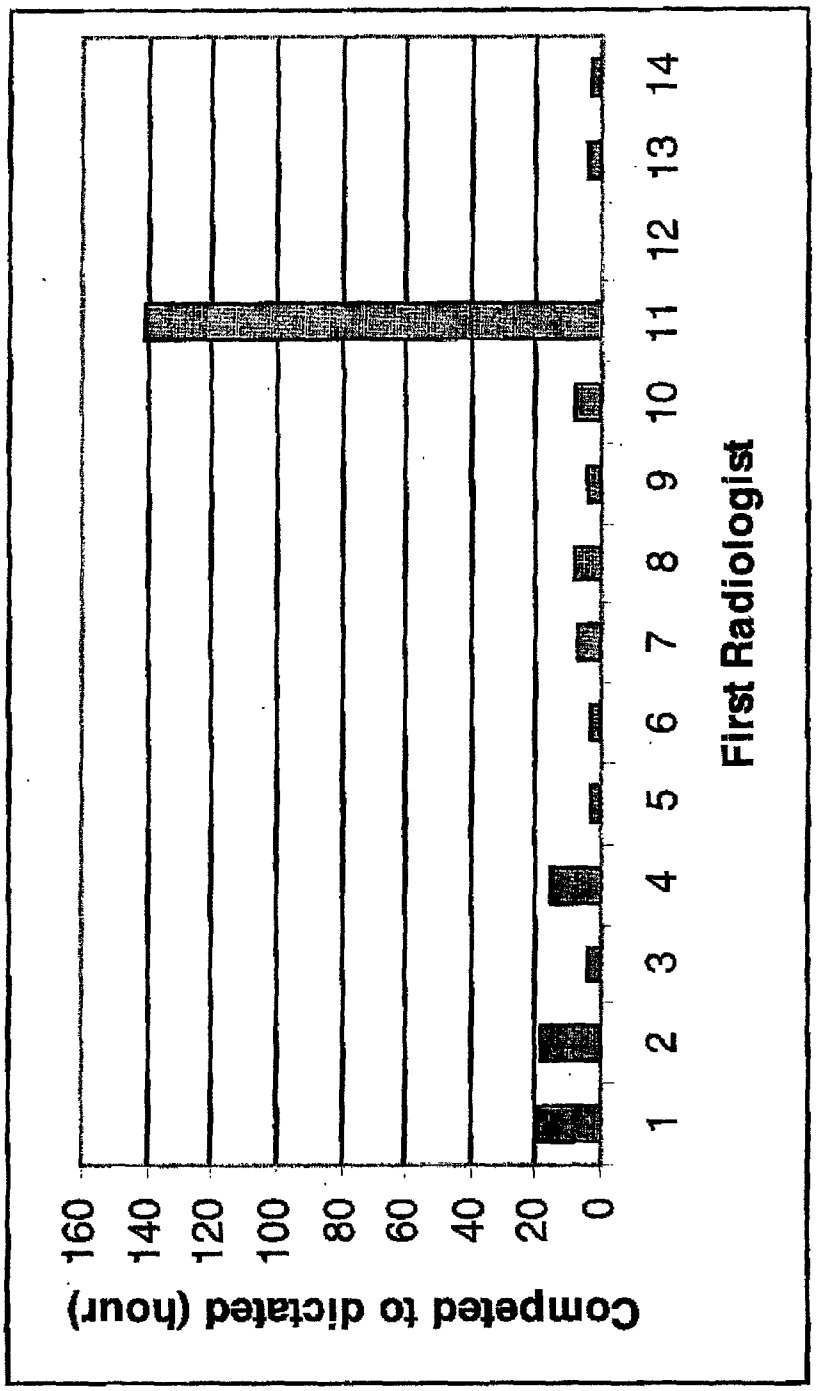
*Units in days; only positive values

* MZ has statistically significant longer completion to departure time than AC

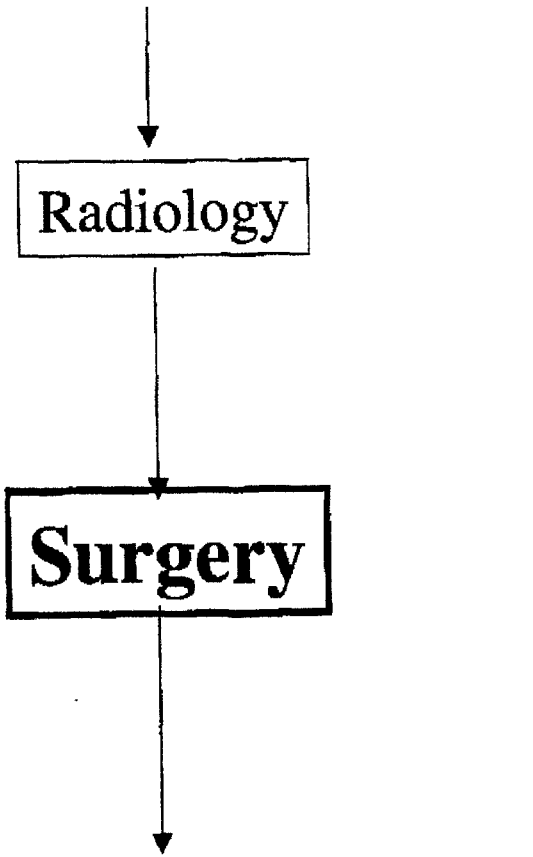
Completion to Dictation

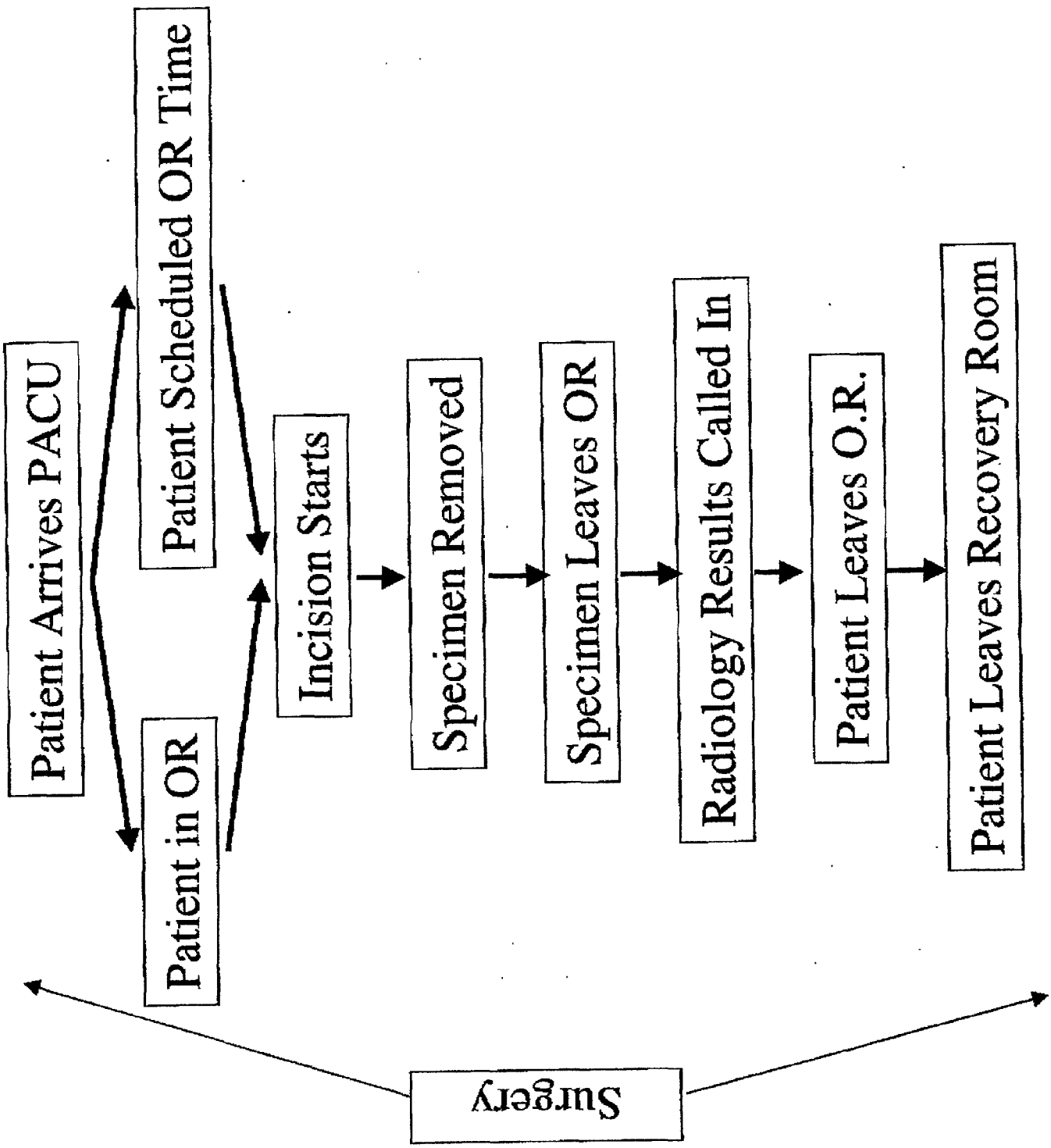
- Mean: 10 hours 46 min.
- Standard deviation: 8 hours 34 min.
- Key independent variable:
  - Radiologist

Completion to Dictation - by Radiologist



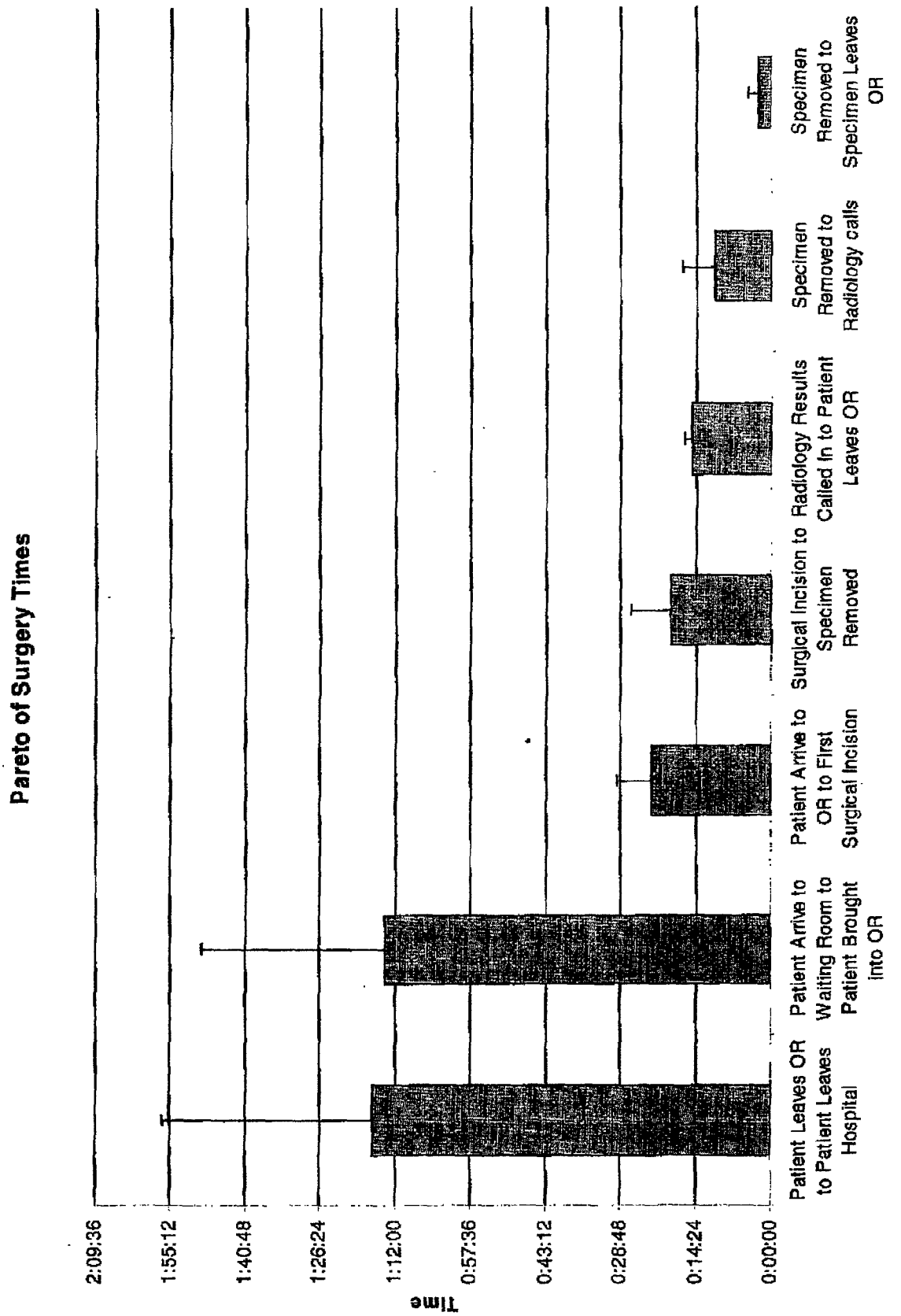
Time Variation Analysis by Department




Patient Arrives PACU
Patient Scheduled OR Time
Patient in OR
Incision Starts
Specimen Removed
Specimen Leaves OR
Radiology Results Called In
Patient Leaves O.R.
Patient Leaves Recovery Room
Surgery

Surgery Data

- 12 data points over 6 weeks
- 75% response rate
- Ask the nurse to fill out form and fax to us.


Pareto of Surgery Times
Time
2:09:36
1:55:12
1:40:48
1:26:24
1:12:00
0:57:36
0:43:12
0:28:48
0:14:24
0:00:00
Patient Leaves OR to Patient Leaves Hospital
Patient Arrive to Waiting Room to Patient Brought into OR
Patient Arrive to OR to First Surgical Incision
Surgical Incision to Specimen Removed
Radiology Results Called In to Patient Leaves OR
Specimen Removed to Radiology calls
Specimen Removed to Specimen Leaves OR

Conclusions

Radiology: Needle Placement
Schedule Exam
Patient Arrives
Scheduled Beginning Time for Exam
Actual Beginning Time for Exam
Exam Completed
Patient Leaves for OR
Exam Dictated and Transcribed
- Specific site (MZ) had a shorter wait time
- Specific referring physicians have shorter patient wait times
-Specific site (MZ) had a shorter wait time
-Different radiologists had different wait times

Radiology: Needle Placement
Schedule Exam
Patient Arrives
Scheduled Beginning Time for Exam
Actual Beginning Time for Exam
Exam Completed
Patient Leaves for OR
Exam Dictated and Transcribed
- Specific site (MZ) had shorter procedure time
- Referring institution effects procedure time
- Specific radiologists have shorter procedure times
- A second radiologist effects procedure time
- The referring physicians effects procedure times
-Specific site (AC) had shorter wait time
-Specific radiologists have shorter wait times
-Specific radiologists have shorter completion to dictated times

Further Studies

- At each specific time point,we have identified which independent variables effect quality/time
- Identify special causes: reduce variation
- Next question: why does this occur? Are there different protocols the institution/physician uses that drives these findings:moving variation
- Collect more data on surgery time flow

Appendix L

Breast Care Center Patient Satisfaction Feedback

Date of Appointment _____
MD_____
Age _____

1. I heard about the Breast Care Center through:
   - ❑ Primary Care/ Ob-Gyn MD referral
   - ❑ Friend
   - ❑ Breast Care Center Patient
   - ❑ TV/ Radio/ Newspaper
   - ❑ Internet ❑ Other: _____

2. I came in here today for a:
   - ❑ Breast lump evaluation
   - ❑ Nipple discharge
   - ❑ Abnormal-mammogram
   - ❑ Second opinion
   - ❑ To see an oncologist, I have breast cancer
   - ❑ Other: _____

3. I was given an appointment within _____ days of my phone call.

4a. When I leave a message for a nurse/doctor, my call is returned within a reasonable period of time.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

4b. I expect a call back within:
   - ❑ 30 minutes ❑ 1-2 hours
   - ❑ same day ❑ next day

5. When I called the Breast Care Center, I was able to speak with someone within a reasonable amount of time without excessive holding.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

6. When I called to make an appointment, I was given one within a reasonable period of time.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

7. In my opinion, a new patient should be given an appointment within:
   - ❑ Same day ❑ 1-2 days ❑ 3-4 days
   - ❑ 1 week ❑ 1-2 weeks

of the phone call.

8. The staff person who scheduled my appointment made me feel like I was being taken care of.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

9. The registration process was satisfactory.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

10. The Front Desk staff were courteous and acknowledged me in a timely manner.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

11. I found the overall appearance of the clinic satisfactory and was comfortable in the waiting area.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

12. I was comfortable with the amount of time that I waited to see the doctor.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

13. After arriving for my appointment, I waited:
   - ❑ 0-30 minutes ❑ 30-45 minutes
   - ❑ 45-60 minutes ❑ 1 -1&1/2 hour
   - ❑ 2+ hours..... until I met the doctor/nurse.

14. I was kept informed of any delays during my visit.
   - ❑ agree ❑ somewhat agree
   - ❑ disagree ❑ somewhat disagree

Comments:

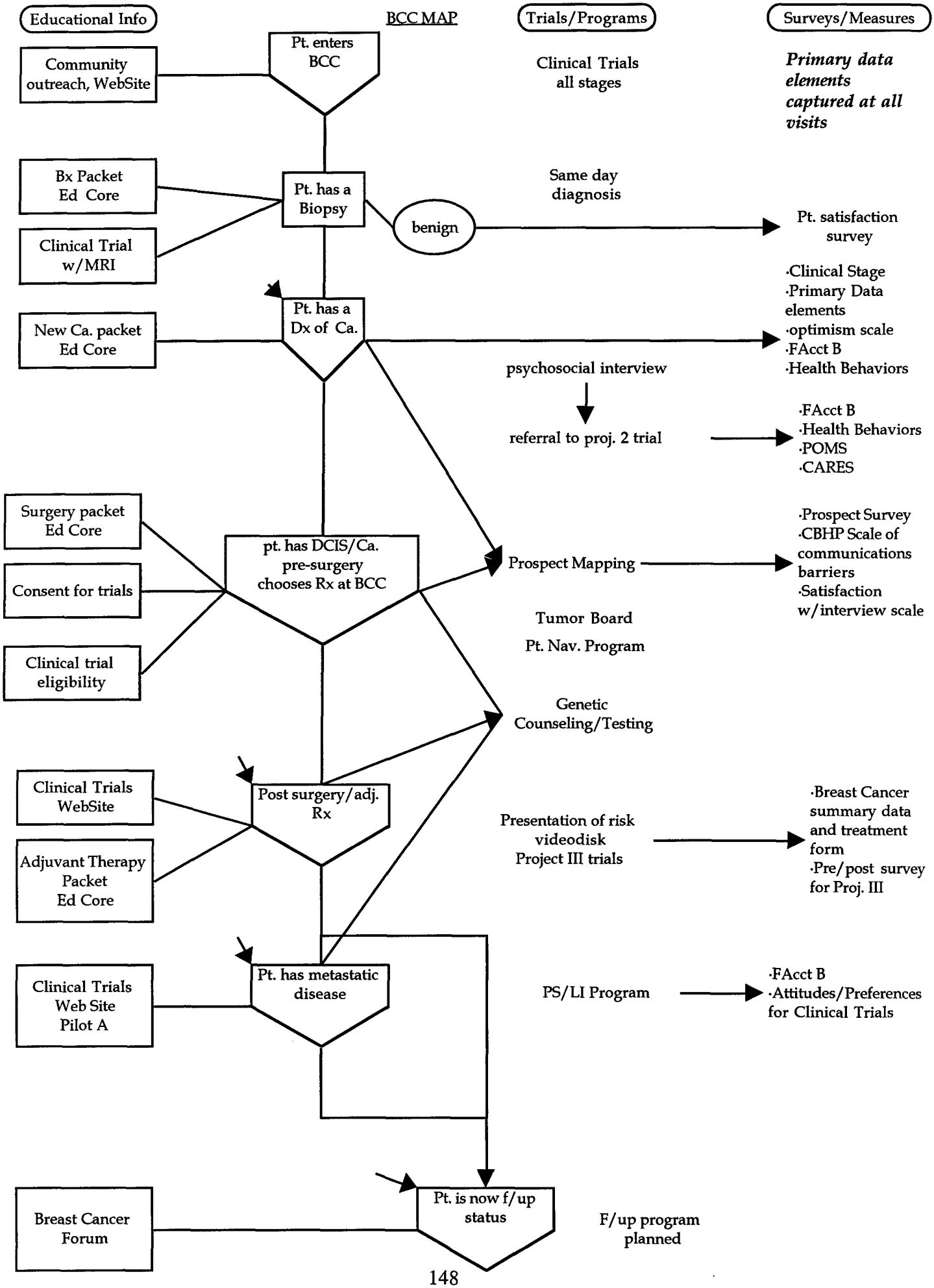
15. I would rate my overall satisfaction with today's visit as:
   - ❑ Excellent ❑ Good ❑ Fair ❑ Poor

16. I would rate my overall satisfaction with my interaction with the staff as follows:

Front Desk staff (receptionists):
❑ Excellent ❑ Good ❑ Fair ❑ Poor
Medical Assistant:
❑ Excellent ❑ Good ❑ Fair ❑ Poor
Nurse(s):
❑ Excellent ❑ Good ❑ Fair ❑ Poor
Doctor(s):
❑ Excellent ❑ Good ❑ Fair ❑ Poor

17. Is there anyone in particular who was especially helpful to you?
If so, who?_____

Name (optional): _____


Educational Info
BCC MAP
Trials/Programs
Surveys/Measures
Community outreach, WebSite
Pt. enters BCC
Clinical Trials all stages
Primary data elements captured at all visits
Bx Packet Ed Core
Clinical Trial w/MRI
Pt. has a Biopsy
Same day diagnosis
benign
Pt. satisfaction survey
New Ca. packet Ed Core
Pt. has a Dx of Ca.
·Clinical Stage
·Primary Data elements
·optimism scale
·FAcct B
·Health Behaviors
psychosocial interview
referral to proj. 2 trial
·FAcct B
·Health Behaviors
·POMS
·CARES
Surgery packet Ed Core
Consent for trials
Clinical trial eligibility
pt. has DCIS/Ca. pre-surgery chooses Rx at BCC
Prospect Mapping
·Prospect Survey
·CBHP Scale of communications barriers
·Satisfaction w/interview scale
Tumor Board
Pt. Nav. Program
Genetic Counseling/Testing
Clinical Trials WebSite
Adjuvant Therapy Packet Ed Core
Post surgery/adj. Rx
Presentation of risk videodisk Project III trials
·Breast Cancer summary data and treatment form
·Pre/post survey for Proj. III
Clinical Trials Web Site Pilot A
Pt. has metastatic disease
PS/LI Program
·FAcct B
·Attitudes/Preferences for Clinical Trials
Breast Cancer Forum
Pt. is now f/up status
F/up program planned

UCSF Mammography Follow-up Study - Patient Questionnaire I

INTRO **Hello, my name is _____ and I'm calling on behalf of** <<SITE NAME>>.

1 PROCEED TO NEXT QUESTION
2 No answer
3 Normal busy
4 Answering machine
5 Do not wish to dial this number (Null attempt)
6 Callback
7 Non-Working Number

S2 **May I speak with** <<NAME OF WOMAN>>**?**

1 Respondent is on the phone (continue)
2 Respondent is available and coming to phone
3 Respondent not available (SCHEDULE CALLBACK)
4 No such person (TERMINATE)
5 No, refused (TERMINATE)

S3 **Hello, my name is _____. I'm calling on behalf of** <SITE NAME>.

We are calling women who have received a mammogram at <SITE NAME> as part of a study about the quality of care for women after their mammogram. The results of this study may help to improve the quality of care for women who receive mammograms. Not too long ago we mailed you a letter explaining this study. Do you remember receiving that letter?

1 Yes
2 No
8 Don't know / Not sure
9 Refused [ATTEMPT TO EXPLAIN, IF STILL REFUSES ➔THANK, TERMINATE]

S4 Let me take a minute to explain what was in the letter. As part of this study we are asking you to complete a telephone interview today and a second telephone interview when we call you again eight months from now. Each interview only takes about 15 minutes and asks about such things as your age, marital status, your general health, your recent mammogram, any medical evaluation you may have had and your satisfaction with the care you received.

(PRESS 1 TO CONTINUE)

S5 All the information you provide will be kept confidential. We will not release it to anyone, including your doctor. Participation in this study is voluntary. You may skip any questions you do not feel comfortable answering and you can stop the interview at any time.

(PRESS 1 TO CONTINUE)

Q1. Would you like to participate in this study?

1 Yes
2 No ➔ [THANK, TERMINATE]

Q1a. Thank you for agreeing to participate. As I said, this interview should take about 15 minutes. Please answer each question as best you can. There are no right or wrong answers, only your best answers. The following questions are about your breast health and the recent mammogram that you received on <<DATE OF MAMMOGRAM>>.

Q2. During the last 6 months prior to this mammogram, have you had any of the following breast concerns:

Q2A. A lump in your breast

1	Yes →	**Q2A1** When did you first notice this?	1	ENTER DATE: ___/___/___ **Q2A2**
2	No		8	Don't Know
8	Don't Know		9	Refused
9	Refused			

Q2B. Have you had discharge from one or both nipples?

1	Yes →	**Q2B1** When did you first notice this?	1	ENTER DATE: ___/___/___ **Q2B2**
2	No		8	Don't Know
8	Don't Know		9	Refused
9	Refused			

Q3. Did you get your recent mammogram because you asked for one or because your clinician recommended one?

1 Asked for one
2 Clinician recommended (includes routine, get one every year)
8 Don't Know
9 REFUSED

Q3A. In the month or two before this <<MAMDATE>> **mammogram, how many other mammograms did you receive?**

1 None
2 Enter Number → **Q3A_NUM** _____ (Range = 1 - 4)

8 Don't Know
9 Refused

Q4. [IF Q3a = 2 INSERT: **Thinking about that first mammogram,**]
were you able to get the appointment for that mammogram as soon as you wanted?

1 Yes
2 No
8 Don't Know
9 REFUSED

Q5. For the mammogram you received on <<MAMDATE>>, how were you given the results of that mammogram?

(CHOOSE ALL THAT APPLY)

1 In person
2 By phone
3 By mail
4 Never received results [SKIP TO Q9]
5 Other (specify): _____
8 DON'T KNOW
9 REFUSED
10 PROCEED TO NEXT QUESTION

Q6. How long after your mammogram did you get the result?

1 Same day of mammogram
2 Day after mammogram
3 Week of mammogram
4 1 - 2 weeks after mammogram
5 More than 2 weeks after mammogram
6 Never received results ➔[SKIP TO Q9]
8 Don't remember/Don't know ➔[SKIP TO Q9]
9 Refused ➔[SKIP TO Q9]

Q7. Do you feel that you had to wait too long to get the results of your mammogram?

1 Yes
2 No
8 Don't Know
9 Refused

Q8. How would you rate the explanation given to you on the day you received the results of your mammogram? Would you say ... [READ LIST]

1 Excellent
2 Very good
3 Good
4 Fair
5 Poor

8 (DO NOT READ) Don't Know
9 (DO NOT READ) Refused

Q9. Since your recent mammogram, please tell me whether you consulted any of these health care providers to further evaluate this mammogram or discuss your breast concerns.

Q9A. A Primary Care Provider

1	Yes →	**Q9A1**	[IF YES] How many different **Primary Care Providers**?
2	No	1	Enter Number _____ **Q9A2**
8	Don't Know	8	Don't Know
9	Refused	9	Refused

Q9B.An "O-b-G-y-n"

1	Yes →	**Q9B1**	[IF YES] How many different "**O-b-G-y-n"s**?
2	No	1	Enter Number _____ **Q9B2**
8	Don't Know	8	Don't Know
9	Refused	9	Refused

Q9C. A Surgeon

1	Yes →	**Q9C1**	[IF YES] How many different **Surgeons**?
2	No	1	Enter Number _____ **Q9C2**
8	Don't Know	8	Don't Know
9	Refused	9	Refused

Q9D. A Nurse Practitioner

1	Yes →	**Q9D1**	[IF YES] How many different **Nurse Practitioners**?
2	No	1	Enter Number _____ **Q9D2**
8	Don't Know	8	Don't Know
9	Refused	9	Refused

Q9E. Another Radiologist

1	Yes →	**Q9E1**	[IF YES] How many **Other Radiologists**?
2	No	1	Enter Number _____ **Q9E2**
8	Don't Know	8	Don't Know
9	Refused	9	Refused

Q10. What was the date of your last clinical breast exam performed by your clinician?

1 ENTER DATE: **Q10_DATE** ___/___/___
8 Don't Know
9 Refused

Q11. Since your mammogram on <<MAMDATE>>, have you received any additional mammograms?

1 Yes → **Q11A** [IF YES] How many?
2 No
8 Don't Know
9 Refused

1 Enter number: _____ **Q11A1**
8 Don't Know
9 Refused

[IF YES TO Q11] **What was/were the date(s) of the additional mammogram(s) since <<MAMDATE>>?**

Q11B 1 Enter First Date **Q11B_1** ___/___/___
8 Don't Know
9 Refused

Q11C 1 Enter Second Date **Q11C_1** ___/___/___
8 Don't Know
9 Refused

Q11D 1 Enter Third Date **Q11D_1** ___/___/___
8 Don't Know
9 Refused

Q12. Since your mammogram on <<MAMDATE>> , have you received an ultrasound of your breast?

1 Yes →
2 No (SKIP TO Q15)
8 Don't Know (SKIP TO Q15)
9 Refused (SKIP TO Q15)

Q12A. What was the date of the ultrasound?
1 Enter Date **Q12A1** ___/___/___
8 Don't Know
9 Refused

Q13. Do you feel like you had to wait too long to have the ultrasound performed?

1 Yes
2 No
8 Don't Know
9 Refused

Q14. Was a cyst aspiration performed at the time of the ultrasound (fluid removed from your breast with a needle)?

1 Yes
2 No
8 Don't Know
9 Refused

Q15. After your recent mammogram, was a breast biopsy recommended?

1 Yes
2 No
8 Don't Know
9 Refused

Q16. Have you received a NEEDLE biopsy of your breast? A needle biopsy is done with a small needle like one used to draw blood from your arm. The needle is used to take out a small piece of breast tissue. Did you have this procedure done?

1 Yes →
2 No (SKIP TO Q18)
8 Don't Know (SKIP TO Q18)
9 Refused (SKIP TO Q18)

Q16A1. What was the date?
1 Enter Date **Q16A2** ___/___/___
8 Don't Know
9 Refused

Q17. Do you feel that you had to wait too long to have this biopsy performed?

1 Yes
2 No
8 Don't Know
9 Refused

Q18. Have you received an "OPEN" or "SURGICAL" biopsy of your breast?

1 Yes →
2 No (SKIP TO Q20)
8 Don't Know (SKIP TO Q20)
9 Refused (SKIP TO Q20)

Q18A. What was the date?
1 Enter Date **Q18A2** ___/___/___
8 Don't Know
9 Refused

Q19. Do you feel that you had to wait too long to have this biopsy performed?

1 Yes
2 No
8 Don't Know
9 Refused

Q20. After you completed all of your tests, what did your clinician tell you that you had?

1 Everything was normal
2 A fibroadenoma
3 Cysts
4 Cancer
5 OTHER (specify)_____
6 Tests still in progress
7 Tests completed but do not yet know results
8 Don't Know
9 Refused

Q21. At the present time, do you believe you need any additional tests to further evaluate your mammogram or breast concerns during the next 12 months?

1 Yes
2 No (SKIP TO Q23)
8 Don't Know (SKIP TO Q23)
9 Refused (SKIP TO Q23)

Q22. Please tell me if you believe you need any of these tests during the next 12 months:
(PRESS ANY KEY TO CONTINUE)

Q22A. A clinical breast exam

1 Yes
2 No
8 Don't Know
9 Refused

Q22B. An additional mammogram

1 Yes
2 No
8 Don't Know
9 Refused

Q22C. An ultrasound

1 Yes
2 No
8 Don't Know
9 Refused

Q22D. A fine needle aspiration

1 Yes
2 No
8 Don't Know
9 Refused

Q22E. A biopsy

1 Yes
2 No
8 Don't Know
9 Refused

Q23. The following questions apply to any breast evaluation that you have had in the past, before your recent mammogram on <<MAMDATE>>. [PRESS ANY KEY TO CONTINUE]

Q23A BEFORE your mammogram on << MAMDATE >>**, have you ever had an abnormal mammogram?**

1 Yes ➔
2 No [SKIP TO Q24]
8 Don't Know [SKIP TO Q24]
9 Refused [SKIP TO Q24]

Q23A1 What was the date?
1 Enter Date **Q23A2** ___/___/___
8 Don't Know
9 Refused

Q24. BEFORE your mammogram on << MAMDATE >> **have you ever had a breast biopsy?**

1 Yes ➔
2 No [SKIP TO Q25A]
8 Don't Know [SKIP TO Q25A]
9 Refused [SKIP TO Q25A]

Q24A. What was the date?
1 Enter Date **Q24A2** ___/___/___
8 Don't Know
9 Refused

Q25A. The following questions are about your experiences with health care providers and related services for your breast concern.

Please tell me whether you agree definitely, somewhat or not at all with each of these statements.

The X-ray technologist was kind and compassionate.
Do you agree definitely, somewhat or not at all?

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25B. The doctors and nurses in my primary care physician's office gave me enough reassurance and support.
Do you agree definitely, somewhat or not at all?

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25C. The doctors spent enough time with me.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25D. I felt like a doctor was in charge of coordinating the follow-up of my mammogram or breast concern.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25E. The doctors adequately addressed my questions and concerns.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25F. The information provided by the nurses in my primary care physician's office was helpful and understandable.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25G. The nurses were kind and compassionate.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25H. My exams and tests were very thorough.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25I. The recommendations for my treatment were thoroughly explained.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q25J. I was very well informed about what would happen to me during my tests.

1 Definitely
2 Somewhat
3 Not at All

4 Did not have any such provider/service
8 Don't remember/Don't know
9 Refused

Q26A. I am now going to read some statements regarding your experiences with your doctors as it relates to you making decisions about your recent breast concern.

. **How often did your doctor explain what he or she was doing? Would you say always, sometimes or never?**

1 Always
2 Sometimes
3 Never

8 Don't remember/Don't know
9 Refused

Q26B. How often did your doctor listen carefully to what you had to say?

(Would you say ...)

1 Always
2 Sometimes
3 Never

8 Don't remember/Don't know
9 Refused

Q26C. (How often did your doctor)
give you enough information about possible tests and treatments?

(Would you say ...)

1 Always
2 Sometimes
3 Never

8 Don't remember/Don't know
9 Refused

Q26D. (How often did your doctor)
give you confusing or contradictory information?

(Would you say ...)

1 Always
2 Sometimes
3 Never

8 Don't remember/Don't know
9 Refused

Q26E. (How often did your doctor)
give you enough say in making decisions about further tests and treatments?

(Would you say ...)

1 Always
2 Sometimes
3 Never

8 Don't remember/Don't know
9 Refused

Q27A. Thinking about the health care services you have received for your mammogram and breast concern, how would you rate each of the following:

The ease of making appointments for your breast care by telephone. Would you rate this service as poor, good, or excellent?

1 Poor
2 Good
3 Excellent

7 Did not make appointments by telephone
8 Don't remember/Don't know
9 Refused

Q27B. The length of time that you waited between making an appointment and the day of your visit (Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27C. The friendliness and courtesy shown to you by the receptionist and appointment clerks (Would rate this as …) [REDA LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27D. The length of time you waited in the reception area until you were seen (Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27E. The amount of time you have with your doctors and staff during a visit (Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27F. How well the whole system worked together to coordinate your medical care, including how well different people and departments communicated with each other.
(Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27G. Your access to specialists
(Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27H. The time it usually took for your provider's office to return your call
(Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27I. The personal interest given to you and your medical problems
(Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q27J. The overall quality of care and services you received to follow-up on your mammogram result or breast concern.
(Would rate this as …) [READ LIST]

1 Poor
2 Good
3 Excellent

8 (DO NOT READ) Don't remember/Don't know
9 (DO NOT READ) Refused

Q28A. These next questions are about how you felt when you found out you had a breast concern. Were you very worried, somewhat worried or not at all worried?

1 Very
2 Somewhat
3 Not at all

8 Don't remember/Don't know
9 Refused

Q28B. Were you very calm, somewhat calm or not at all calm?

1 Very
2 Somewhat
3 Not at all

8 Don't remember/Don't know
9 Refused

Q28C. Were you very depressed, somewhat depressed or not at all depressed?

1 Very
2 Somewhat
3 Not at all

8 Don't remember/Don't know
9 Refused

Q28D. Were you very hopeful, somewhat hopeful or not at all hopeful?

1 Very
2 Somewhat
3 Not at all

8 Don't remember/Don't know
9 Refused

Q28E. Were you very anxious, somewhat anxious or not at all anxious?

1 Very
2 Somewhat
3 Not at all

8 Don't remember/Don't know
9 Refused

Q29. How reassured were you by the follow-up tests and visits that you have had for your breast concern? Would you say not at all reassured, a little, somewhat, very or extremely reassured?

1 Not at all
2 A little
3 Somewhat
4 Very
5 Extremely

8 Don't remember/Don't know
9 Refused

Q30. How intense was the fear or anxiety you experienced as a result of your recent mammogram or breast evaluation? Would you say not at all intense, a little, somewhat, very or extremely intense?

1 Not at all
2 A little
3 Somewhat
4 Very
5 Extremely

8 Don't remember/Don't know
9 Refused

Q31. During the past month, how often have you worried about the possibility that you might develop breast cancer? Would you say not at all, rarely, occasionally, often or all the time?

1 Not at all
2 Rarely
3 Occasionally
4 Often
5 All the time

8 Don't remember/Don't know
9 Refused

Q32. During the past month, how often have thoughts about breast cancer spilled over or intruded into your daily activities?

1 Not at all
2 Rarely
3 Occasionally
4 Often
5 All the time

8 Don't remember/Don't know
9 Refused

Q33. The following questions are about your general health. Currently, would you describe your overall health as . . . [READ LIST]

1 Excellent
2 Very good
3 Good
4 Fair
5 Poor

8 (DO NOT READ) Don't know
9 (DO NOT READ) Refused

Q34. Compared to 12 months ago, would you say that your health is currently better, worse or the same?

1 Better
2 Worse
3 Same
8 Don't know
9 Refused

Q35A. How much does your health now limit you in performing MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? Would you say you are limited a lot, a little or not at all?

1 A lot
2 A little
3 Not at all
8 Don't know
9 Refused

Q35B. And how much does your health now limit you in climbing several flights of stairs? Would you say you are limited a lot, a little or not at all?

1 A lot
2 A little
3 Not at all
8 Don't know
9 Refused

Q36A. During the past <u>4 weeks</u>, have you accomplished less than you wanted to in your work or other daily activities as the result of your physical health?

1 Yes
2 No
8 Don't know
9 Refused

Q36B. Also as a result of your physical health during the past 4 weeks, were you limited in the kind of work or types of activities you could do?

1 Yes
2 No
8 Don't know
9 Refused

Q37A. During the past 4 weeks, have you accomplished less than you wanted to in your work or other daily activities as a result of any emotional problems, such as feeling depressed or anxious?

1 Yes
2 No
8 Don't know
9 Refused

Q37B. Also as a result of any emotional problems, such as feeling depressed or anxious during the past 4 weeks, were you limited in the kind of work or types of activities you could do?

1 Yes
2 No
8 Don't know
9 Refused

Q38. During the past 4 weeks, how much did pain interfere with your normal work including both work outside the home and housework? Would you say... [READ LIST]

1 Not at all
2 A little bit
3 Moderately
4 Quite a bit
5 Extremely

8 (DO NOT READ) Don't know
9 (DO NOT READ) Refused

Q39A How much of the time during the past 4 weeks have you felt calm and peaceful? Would you say all of the time, most of the time, some of the time, a little of the time or none of the time?

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

8 Don't know
9 Refused

Q39B How much of the time during the past 4 weeks did you have a lot of energy? Would you say all of the time, most of the time, some of the time, a little of the time or none of the time?

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

8 Don't know
9 Refused

Q39C How much of the time during the past 4 weeks have you felt downhearted and blue? Would you say all of the time, most of the time, some of the time, a little of the time or none of the time?

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

8 Don't know
9 Refused

Q40. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities, like visiting with friends or relatives? Would you say all of the time, most of the time, some of the time, a little of the time or none of the time?

1 All of the time
2 Most of the time
3 Some of the time
4 A little of the time
5 None of the time

8 Don't know
9 Refused

Q41A Please tell me yes or no, has a doctor ever told you that you had any of these problems..... Lung problems, such as asthma, chronic bronchitis, emphysema or other lung problems

1 Yes
2 No
8 Don't know
9 Refused

Q41B. Heart disease or high blood pressure

1 Yes
2 No
8 Don't know
9 Refused

Q41C. Diabetes or high blood sugar

1 Yes
2 No
8 Don't know
9 Refused

Q41D. Problems with your stomach, gall bladder, liver or kidneys

1 Yes
2 No
8 Don't know
9 Refused

Q41E. Hearing or eye problems

1 Yes
2 No
8 Don't know
9 Refused

Q41F. Cancer

1 Yes
2 No
8 Don't know
9 Refused

Q41G. Depression

1 Yes
2 No
8 Don't know
9 Refused

Q42A. These questions are about breast cancer among your female blood relatives. Has your mother ever had breast cancer?

1 Yes
2 No
3 Biological mother unknown
8 Don't know
9 Refused

Q42B. Have any of your sisters ever had breast cancer?

1 Yes
2 No
3 No sisters or sisters unknown
8 Don't know
9 Refused

Q42C. How about your mother's mother, has she had breast cancer?

1 Yes
2 No
3 Biological grandmother unknown
8 Don't know
9 Refused

Q42D. Your mother's sisters?

1 Yes
2 No
3 No biological aunt or aunt unknown
8 Don't know
9 Refused

Q42E. And have any of your daughters ever had breast cancer?

1 Yes
2 No
3 No daughters or daughters unknown
8 Don't know
9 Refused

Q43. And finally, my last set of questions. How old were you on your last birthday?

_____ Years (Range = 18 to 100)
999 = Refused

Q44. Have you gone through menopause or "the change"?

1 Yes
2 No
8 Don't know
9 Refused

Q45. What is your current marital status? [READ LIST]

1 Single
2 Married
3 Legally Separated
4 Divorced
5 Widowed
9 [DO NOT READ] Refused

Q46. What is the highest year of school that you have completed?

1 Grade 1
2 Grade 2
3 Grade 3
4 Grade 4
5 Grade 5
6 Grade 6
7 Grade 7
8 Grade 8
9 HS freshman
10 HS sophomore
11 HS junior
12 HS graduate
13 Some college education/technical school/Jr. College graduate
14 College graduate
15 Post-graduate education
16 Master's degree
17 Doctorate
99 Decline to state/Refused

Q47. Which of the following groups best describes your racial or ethnic background? [READ LIST]

1 Asian/Pacific Islander or Asian-American
2 Black or African-American
3 Hispanic or Latino
4 Native American
5 White or Caucasian
6 (DO NOT READ) Other (specify): **Q47_TXT** _____
99 (DO NOT READ) Decline to state/Refused

Q48. Were you born in the United States?

1 Yes [SKIP TO Q49]
2 No → **Q48A. In what country were you born?** _____
9 Decline to state/Refused [SKIP TO Q49]

Q49. Do you have trouble talking with your doctor because of language preference?

1 Yes
2 No
8 Don't Know
9 Refused

Q50. In the past month, how many family members or close personal friends could you talk with about your personal problems?

1 None
2 Enter specific number: **Q50_2** _____ (1-250)
8 Don't know
9 Refused

Q51. Which of the following best describes your current occupational position?
[READ LIST]

1 Employed for a wage or salary
2 Self-employed
3 Work without pay in family business or firm
4 Retired
5 Homemaker
6 Student
7 Unemployed
8 Other Specify: **Q51_TXT** _____
9 Don't Know
10 Refused

Q52. Which of the following is your family's current annual income – that would be the total pre-tax income from all sources earned in the past year by all members of your family?
[READ LIST]

1 Less than $15,000
2 $15,001 to 30,000
3 $30,001 to 45,000
4 $45,001 to 60,000
5 $60,001 to 75,000
6 over $75,000

8 (DO NOT READ) Don't know
9 (DO NOT READ) Refused

Q53. Including yourself, how many people live in your household as members of your family?

1 Enter Number of household members: **Q53_TXT** _____
8 Don't know
9 Refused

Q54. In the past 12 months, did you have health insurance?

1 Yes
2 No (SKIP TO Q55)
8 Don't know (SKIP TO END)
9 Refused (SKIP TO END)

Q54A. How long have you had this kind of insurance?

1 Less than 6 months
2 6 - 11 months
3 1 - 2 years
4 More than 2 years
8 Don't know (SKIP TO END)
9 Refused (SKIP TO END)

Q54B. How adequate is your health insurance coverage? Would you say [READ LIST]

1 Very adequate
2 Somewhat adequate
3 Somewhat inadequate
4 Very inadequate

8 (DO NOT READ) Don't know
9 (DO NOT READ) Refused

Q54C. What is the main type of health insurance that you have at this time?

[CHOOSE ONE]

1 HMO
2 Private Fee for Service
3 Medicare
4 Medi-Cal
5 Other (Specify): **Q54C_TXT** _____
8 Don't know
9 Refused

[IF Q54=1 SKIP TO END]

Q55. How long have you been without coverage?

1 Never had health insurance
2 Less than 6 months
3 6 - 11 months
4 1 - 2 years
5 More than 2 years

8 Don't know
9 Refused

END

That's my last question. Thank you for your cooperation and for being part of this study. We will call you again in about eight months to do one more interview.

Project 4

Appendices

Stance Toward Collaboration Scale

Please place a check mark after the one (and only one) statement of the five below that best summarizes your feelings about who should make any decisions that need to be made in the course of your upcoming consultation:

1. Dr. A should make the decisions using all that Dr. A knows or can learn, without regard to my opinion. ☐

2. Dr. A should make the decisions but strongly consider my opinion. ☐

3. Dr. A and I should make the decisions together, on an equal basis. ☐

4. I should make the decisions but strongly consider Dr. A's opinion. ☐

5. I should make the decisions using all I know or can learn, without regard to Dr. A's opinion. ☐

Remember to mark only one box, please!

CBHP Scale of Communication Barriers

Marking one box only for each, please indicate to what extent the following statements are true for you as you approach your next consultation with your doctor, whom we'll refer to as Dr. A.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I'm in information overload.	[ ]	[ ]	[ ]	[ ]	[ ]
2. I know how to talk—not just agree—with Dr. A.	[ ]	[ ]	[ ]	[ ]	[ ]
3. I don't know how to question Dr. A.	[ ]	[ ]	[ ]	[ ]	[ ]
4. I know what questions to ask Dr. A.	[ ]	[ ]	[ ]	[ ]	[ ]
5. I expect to withhold some of my concerns for fear of wasting Dr. A's time.	[ ]	[ ]	[ ]	[ ]	[ ]
6. I expect to withhold some of my questions for fear that Dr. A will think they're stupid.	[ ]	[ ]	[ ]	[ ]	[ ]
7. I expect to withhold some of my concerns for fear that Dr. A will react defensively.	[ ]	[ ]	[ ]	[ ]	[ ]
8. I expect to withhold some of my questions for fear that Dr. A can't admit being ignorant of the answers.	[ ]	[ ]	[ ]	[ ]	[ ]
9. I have chosen to consult Dr. A from among several candidate physicians.	[ ]	[ ]	[ ]	[ ]	[ ]
10. I know where I can go for another opinion, if I need one.	[ ]	[ ]	[ ]	[ ]	[ ]
11. I am having trouble deciding whether to consult any other physicians besides Dr. A.	[ ]	[ ]	[ ]	[ ]	[ ]
12. I know exactly who else I need to see about my concerns.	[ ]	[ ]	[ ]	[ ]	[ ]

Satisfaction with Interview Scale

Please indicate, using the scale below, to what extent each of the following statements is true for you at this time. Mark one box for each statement, please.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. The interview has helped me prepare for the medical consultation that is to follow it.	[ ]	[ ]	[ ]	[ ]	[ ]
2. The benefit I obtained from the interview was definitely worth the time and effort that I put into it.	[ ]	[ ]	[ ]	[ ]	[ ]
3. If I had to do it over again, I'd rather skip the interview and proceed directly to the consultation with the doctor.	[ ]	[ ]	[ ]	[ ]	[ ]
4. I would recommend this type of interview to a friend with an upcoming breast cancer consultation.	[ ]	[ ]	[ ]	[ ]	[ ]
5. I would decline the opportunity to participate in this type of interview before a future breast cancer consultation.	[ ]	[ ]	[ ]	[ ]	[ ]

OYM Decision Clarity Scale

Please indicate the extent to which the following statements are true for you for your upcoming consultation with Dr. A (name:_____).

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. I am having trouble making decisions regarding my medical care.	[ ]	[ ]	[ ]	[ ]	[ ]
2. I have a thorough understanding of the medical diagnosis.	[ ]	[ ]	[ ]	[ ]	[ ]
3. I understand what could happen without any further medical treatment.	[ ]	[ ]	[ ]	[ ]	[ ]
4. I know of at least two treatment options that are often recommended in cases like this.	[ ]	[ ]	[ ]	[ ]	[ ]
5. I do not understand what could happen after each medical treatment option.	[ ]	[ ]	[ ]	[ ]	[ ]
6. I know what is important to me for this decision.	[ ]	[ ]	[ ]	[ ]	[ ]
7. It's not clear to me which treatment option is best.	[ ]	[ ]	[ ]	[ ]	[ ]
8. Dr. A and I agree on a treatment strategy.	[ ]	[ ]	[ ]	[ ]	[ ]
9. I am comfortable with my level of participation in the decisions about treatment.	[ ]	[ ]	[ ]	[ ]	[ ]
10. I am ready to begin treatment to deal with my medical situation.	[ ]	[ ]	[ ]	[ ]	[ ]

UCSF Satisfaction with Consultation Scale

Please indicate to what extent the following statements are true for you as you reflect on your consultation with _____.

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. I am satisfied with the quality of this consultation.	[ ]	[ ]	[ ]	[ ]	[ ]
2. This consultation was more productive than most of my other consultations.	[ ]	[ ]	[ ]	[ ]	[ ]
3. We addressed all of my questions and concerns.	[ ]	[ ]	[ ]	[ ]	[ ]
4. It was easy for me to voice my questions and concerns in the consultation.	[ ]	[ ]	[ ]	[ ]	[ ]
5. I was not able to talk as much as I wanted during the consultation.	[ ]	[ ]	[ ]	[ ]	[ ]
6. I felt overwhelmed at times during the consultation.	[ ]	[ ]	[ ]	[ ]	[ ]
7. I know who is responsible for each of the tasks we identified in this consultation	[ ]	[ ]	[ ]	[ ]	[ ]

The Consultation Planner Training Survey

Name: _____ **Date :** _____ **Time:** _____

	Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
1. The importance of effective patient-physician communication for high-quality medical decision-making is over-rated. (S)	[ ]	[ ]	[ ]	[ ]	[ ]
2. In order to communicate effectively with their physicians, patients must be able to raise and resolve questions and concerns. (S)	[ ]	[ ]	[ ]	[ ]	[ ]
3. In general, patients face barriers to raising and resolving questions and concerns with their physicians. (P)	[ ]	[ ]	[ ]	[ ]	[ ]
4. One of my priorities is to help patients in my organization raise and resolve questions and concerns with their physicians. (I)	[ ]	[ ]	[ ]	[ ]	[ ]
5. I am interested in learning about new tools for helping patients in my organization raise and resolve questions and concerns with their physicians. (I)	[ ]	[ ]	[ ]	[ ]	[ ]
6. Consultation Planning sessions will help patients in my organization raise and resolve questions and concerns with their physicians. (I)	[ ]	[ ]	[ ]	[ ]	[ ]
7. Having DNote software would make it easier to create Consultation Plans. (I)	[ ]	[ ]	[ ]	[ ]	[ ]
8. I would like to help implement Consultation Planning services in my organization. (N-P)	[ ]	[ ]	[ ]	[ ]	[ ]
9. I feel well-prepared to conduct Consultation Planning sessions with patients in my organization.	[ ]	[ ]	[ ]	[ ]	[ ]
10. In the context of all my other opportunities, the most recent training session was not a worthwhile use of my time.	[ ]	[ ]	[ ]	[ ]	[ ]

PATIENT DEMOGRAPHICS

Patient _____ **ID** _____ **DOD ID** _____

Required Information

Medical Record Number _____

Treatment Site ○ CPMC ○ UCSF/Mt. Zion

First *Middle* *Last*

Patient Name _____ _____ _____

Date of Birth _____

Age _____

DOD ID Number _____ (Generated by database)

Optional Information

Sex _____

Alias _____

Ethnic Group _____

Race _____

Language _____

Marital Status _____

Religion _____

SSN _____

Address _____

City/State/Zip _____ _____ _____

County Code _____

Home Phone _____

Work Phone _____

PATIENT MEDICAL HISTORY

Patient _____ **ID** _____ **DOD ID** _____

GYNECOLOGIC HISTORY

Regular Periods ○ Yes ○ No

Menopausal Status _____

Age of Onset _____

Age Periods Stopped _____

# of Pregnancies _____ # of Live Births _____

Average of Breast Feeding Months _____

Method of Birth Control _____

Oral Contraceptive Use _____

GENERAL MEDICAL HISTORY

Key Medical Conditions or none ☐ Yes ☐ No

		Years			Years			Years
Alcoholism	☐ Yes ☐ No		Heart Disease	☐ Yes ☐ No		Diabetes	☐ Yes ☐ No	
Arthritis	☐ Yes ☐ No		High Cholesterol	☐ Yes ☐ No		Thyroid	☐ Yes ☐ No	
Depression	☐ Yes ☐ No		HTN	☐ Yes ☐ No		TB	☐ Yes ☐ No	
Asthma/ Allergies	☐ Yes ☐ No		Kidney Disease	☐ Yes ☐ No		Drug Addiction	☐ Yes ☐ No	

Other Medical Conditions: _____

Other Cancers ☐ None ☐ Stomach ☐ Uterus ☐ Colon ☐ Lymphoma ☐ Other ☐ Cervical ☐ Ovarian ☐ Skin ☐ Lung ☐ Mouth

FAMILY HISTORY

		Relationship to Pt	Age at Diagnosis	Type
Breast cancer	☐ Yes ☐ No			
Other Cancer	☐ Yes ☐ No			

SOCIAL HISTORY

Education Level ○ 8th grade or less ○ High school graduate ○ College graduate ○ Some high school ○ Some college or technical ○ Graduate school

Current Tobacco Use ○ Yes ○ No

Age Quit _____

Prior Tobacco Use ○ Yes ○ No

Packs per day ○ 1/4 ○ 1/2 ○ 1 ○ 2 ○ 3

Number of Years ○ 0-2 ○ 2-5 ○ 5-10 ○ 10-20 ○ >20

Current Alcohol Use ○ Yes ○ No

Recreational drugs ○ Yes ○ No

Prior Alcohol Use ○ Yes ○ No

Type _____

Drinks per week _____

Frequency of use _____

IS DATA SHEET COMPLETE? ○ Yes ○ No

SURGERY / PATHOLOGY / STAGING

Patient _____ **ID** _____ **DOD ID** _____

Menopausal Status at Dx ○ Pre ○ Post ○ Uncertain

Date First Cancer Diagnosis _____ ☐ Month* ☐ Day*

SURGERY TREATMENT

Surgery Completed ○ Y ○ N ○ Pending

Cancer in which Breast ○ L ○ R ○ Bilateral If Bilateral, complete a 2nd surgery sheet

Surgery (check and date all surgery patient has had to date)	*Type*	*Date*	*Estimated**
	☐ Wide excision/Lumpectomy		☐ Month* ☐ Day*
	☐ Subcutaneous Mastectomy		☐ Month* ☐ Day*
	☐ MRM/LND		☐ Month* ☐ Day*
	☐ LND		☐ Month* ☐ Day*

HISTOLOGY

Histology (Check all that apply) ☐ DCIS ☐ Invasive Lobular ☐ Not Known ☐ LCIS ☐ Invasive Ductal ☐ Other *Other:* _____

Margins (from last surgery) ○ Positive ○ Negative ○ Not Known ○ Pending

PATHOLOGY

(from most recent surgery) ○ Pending

Tumor Largest Diameter _____ cm ☐ Microscopic Foci ☐ Size can't be determined

Positive # Nodes _____ Total # Nodes Examined _____ ○ Unknown

ER ○ Positive ○ Negative ○ Indeterminate ○ Not Done ○ Pending ○ U

PR ○ Positive ○ Negative ○ Indeterminate ○ Not Done ○ Pending ○ U

HER2/neu ○ Positive ○ Negative ○ Indeterminate ○ Not Done ○ Pending ○ U

S Phase _____ % ○ Unable to quantify ○ Not done ○ Pending ○ Unknow

Grade
○ I Well Diff- 3,4
○ II Mod Diff- 5,6,7
○ III Poorly Diff- 8,9
○ Unknown

Ploidy Level ○ Aneuploid ○ Diploid ○ Polyploid ○ Not Done ○ Pending ○ Unkno

Ki 67 ○ High ○ Intermediate ○ Low ○ Not Done ○ Pending ○ Unknown

STAGING

Staging complete? ○ Yes ○ No ○ Pending

Staging
○ Tis ○ T0 ○ T1 ○ T2 ○ T3 ○ T4
○ N0 ○ N1 ○ N2 ○ N3
○ M0 ○ M1

Stage Grouping ○ 0 ○ In Situ ○ I ○ IIA ○ IIB ○ IIIA ○ IIIB ○ IV

IS DATA SHEET COMPLETE? ○ Y ○ N

* If precise month and/or day is not known, enter "1" and check which is **not** precise.

ADJUVANT THERAPY

Patient _____ **ID** _____ **DOD ID** _____

Current Menopausal Status ○ Pre ○ Post ○ Uncertain

CHEMOTHERAPY

Received? ○ Y ○ N

Chemo Regimen ○ AC ○ CMF ○ Taxol ○ CAF ○ Other *Other:* _____

Number of Cycles _____

Length of Cycles _____

Start Date _____ ☐ Month* ☐ Day*

End Date _____ ☐ Month* ☐ Day*

Best Response ○ CR ○ PR ○ SD ○ NE or Unknown

HORMONE TREATMENT

Received? ○ Y ○ N

Hormone Treatment ☐ Oophorectomy ☐ Tamoxifen ☐ Other *Other:* _____

Start Date _____ ☐ Month* ☐ Day*

End Date _____ ☐ Month* ☐ Day*

Best Response ○ CR ○ PR ○ SD ○ NE or Unknown

RADIATION THERAPY

Received? ○ Y ○ N

Site of XRT ☐ Breast ☐ Chest Wall ☐ Supraclavicular ☐ Axillary ☐ Other

Other Site _____

Rads of XRT _____

Start Date _____ ☐ Month* ☐ Day*

End Date _____ ☐ Month* ☐ Day*

Additional Site of XRT ☐ Breast ☐ Chest Wall ☐ Supraclavicular ☐ Axillary ☐ Other

Additional Rads _____

Radiation Boost? ○ Y ○ N

Rads of Boost _____

Best Response ○ CR ○ PR ○ SD ○ NE or Unknown

IS DATA SHEET COMPLETE? ○ Y ○ N

* If precise month and/or day is not known, enter "1" and check which is **not** precise.

RECURRENCE - LOCAL/ METASTATIC/ NEW PRIMARY

Patient _____ **ID** _____ **DOD ID** _____

Current Menopausal Status ○ Pre ○ Post ○ Uncertain

Recurrence Type ○ Metastatic Recur ○ Local/Regional Recur ○ New Primary

Histologically Confirmed? ○ Yes ○ No ○ Pending

Date of Recurrence _____ ☐ Month* ☐ Day*

Site of Local Recurrence ☐ Ipsilateral Breast ☐ Chest Wall ☐ Supraclavicular ☐ Axillary

Site of New Primary ○ Left breast ○ Right breast

Site of Metast Recurrence ☐ Bone ☐ Liver ☐ Non-axillar nodes ☐ Skin ☐ Brain ☐ Lung ☐ Other *Other:* _____

PATHOLOGY (Refers to biopsy of recurrence, not initial dx of cancer.)

Biopsy Date _____ ☐ Month* ☐ Day*

ER status ○ Positive ○ Negative ○ Indeterminate ○ Not done ○ Pending

PR status ○ Positive ○ Negative ○ Indeterminate ○ Not done ○ Pending

Ploidy Level ○ Aneuploid ○ Diploid ○ Polyploid ○ Not Done ○ Pending

S phase _____ % ○ Unable to quantify ○ Not done ○ Pending

Grade ○ I Well Diff 3,4 ○ II Mod Diff 5-7 ○ III Poorly Diff 8,9

HER2/Neu ○ Positive ○ Negative ○ Indeterminate ○ Not done ○ Pending

Margins ○ Positive ○ Negative ○ Indeterminate ○ Not done ○ Pending

Ki-67 ○ High ○ Intermediate ○ Low ○ Not done ○ Pending

IS DATA SHEET COMPLETE? ○ Y ○ N

* If precise month and/or day is not known, enter "1" and check which is **not** precise.

TREATMENT FOR METASTATIC/RECURRENT BREAST CANCER

Patient _____ **ID** _____ **DOD ID** _____

Current Menopausal Status ○ Pre ○ Post ○ Uncertain Recurrence Date _____

CHEMOTHERAPY

Received? ○ Yes ○ No

Chemo Regimen ○ AC ○ CMF ○ Taxol ○ CAF ○ HD/BMT-PBSC ○ Other

Other Regimen _____

Number of Cycles _____

Length of Cycles _____

Start Date _____ ☐ Month* ☐ Day*

End Date _____ ☐ Month* ☐ Day*

Best Response ○ CR ○ PR ○ SD ○ NE or Unknown

HORMONE TREATMENT

Received? ○ Yes ○ No

Hormone Treatment ○ Oopherectomy ○ Tamoxifen ○ Other *Other :* _____

Start Date _____ ☐ Month* ☐ Day*

End Date _____ ☐ Month* ☐ Day*

Best Response ○ CR ○ PR ○ SD ○ NE or Unknown

RADIATION THERAPY

Received? ○ Yes ○ No

Site of XRT ☐ Breast ☐ Chest Wall ☐ Supraclavicular ☐ Axillary ☐ Other

Other Site _____

Rads of XRT _____

Start Date _____ ☐ Month* ☐ Day*

End Date _____ ☐ Month* ☐ Day*

Additional Site of XRT _____

Additional Rads _____

Radiation Boost? ○ Yes ○ No

Rads of Boost _____

Best Response ○ CR ○ PR ○ SD ○ NE or Unknown

IS DATA SHEET COMPLETE? ○ Y ○ N

* If precise month and/or day is not known, enter "1" and check which is **not** precise.

686

PHYSICIAN AND PATIENT BARRIERS TO ENROLLMENT ON BREAST CANCER CLINICAL TRIALS. *D. Tripathy, K. Patel, B. Brown, N. Chernyukhin, H. Wallace, F. Hassin, A. MacMillan, L. Esserman. The University of California at San Francisco Cancer Center, San Francisco, CA.*

Fewer than 3% of patients with breast cancer in the U.S. participate in clinical trials, indicating barriers to enrollment both on the side of care providers and patients. Patients with newly diagnosed or progressive breast cancer and physicians who provide care for breast cancer in the San Francisco Bay Area responded to separate surveys covering domains of trial awareness, cost, convenience, risks, potential benefits, and trials in alternative medicine. Patients felt extra time requirements, side effects of new drugs, and reluctance to be randomized are major barriers. Younger patients had more concerns about costs. Worries about insurance coverage were seen in lower income and education groups and confidentiality was a concern in married patients. White patients received more information on the Internet. Non-white patients and those citing a religious preference trusted their doctors to make decisions about trials. English-speaking patients were more concerned about side effects and efficacy of experimental therapy. Physicians identified lack of trial information, patient inconvenience, preference for one treatment arm, office staff time, but not compromise on patient care as important barriers. Younger physicians were more concerned about toxicities of new agents. Medical oncologists compared to other specialists felt a greater restriction of eligibility requirements and were less worried about side effects of new agents. Private practice and non-academic physicians were more concerned about stresses to patients and interference with treatment and referral patterns. Attitudes on trials in alternative medicine were generally positive, especially in younger respondents. Married and higher income patients were more concerned about negative perceptions from family and physicians for participation in alternative medicine trials. Younger physicians had less concern about interference with standard care and loss of patient/physician credibility with participation in alternative trials. Mechanisms to target and address these physician and patient barriers are needed.

DATA ANALYSIS - PILOT A PROJECT

Total No. of Patients entered in Clinical trial at UCSF-Mt. Zion Breast Care Center **220**
(All the patients enrolled in clinical trials are since 6/1/97)

No. of patients entered in Therapeutic Clinical Trials		**45**
CALGB Trials	8904	8
	9640	2
Pharmaceutical Trials		
	957512	1
	957513	17
	95756	5
	95758	1
	967511	2
	97751	1
	97752	2
	97754	1
	96758	2
	95759	0
	96756	1
	957510	2
No. of patients entered in Imaging Trials		**97**
	MS-325-05	
	NIH 69587	
	ACS 97-036-01	
	DOD 1796C6126	
No. of patients entered in Non-therap/Non-Imaging Clinical Trials		**78**
	95985	13
	96753	22
	95-091	18
	64734	10
	DOD (PSYCHOSOCIAL)	15

DATA ANALYSIS - PILOT A PROJECT

No. of Patients entered in DOD Clinical Trial Questionnaire	**150**
No. of patients from this group who entered in clinical trial	**21**
No. of patients entered in Therapeutic Clinical Trials	13
No. of patients entered in Imaging Trials	2
No. of patients entered in Other Clinical Trials	13
Total No. of patients entered in Database	**920**
New Patients (Medical Oncology)	**201**
New Pts./2nd Opinion (Medical Oncology)	**155**
Total No of patients who have Breast Cancer	**754**
Biopsy Diagnosis of Cancer	99
Staging Complete	69
Decision for Adjuvant Rx complete or Adjuvant Rx ongoing/stop	45
Early Stage NED	**294**
Local / Regional Recurrence	**32**
Local / Reg New diagnosis	13
Metastasis	**184**
Metastasis New diagnosis	27
Metastatic Progression	71
Mets. stable/responding	83

No. of Patients whose ER/PR status known	78
ER/PR status at the diagnosisi of cancer	62
ER/PR status for the Mets.	24
ER/PR statis for the Recurrence	4

DATA ANALYSIS - PILOT A PROJECT

STAGE

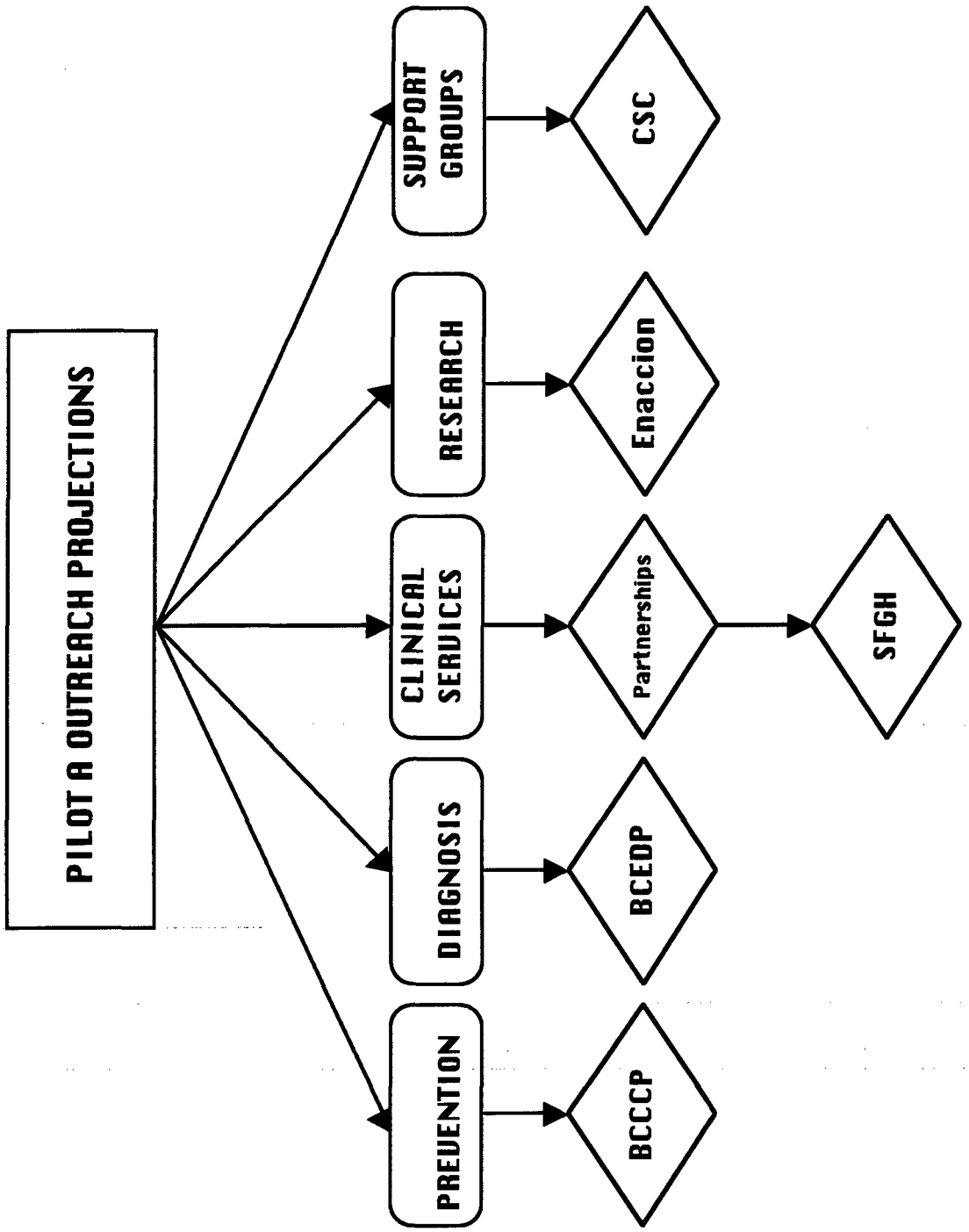
No. of Patients whose stage at the diagnosis of cancer known		**145**
Stage 0		31
Stage I		41
Stage II		61
Stage II A	42	
Stage II B	19	
Stage III		10
Stage III A	7	
Stage III B	3	
Stage IV		12

THERAPY

Patients who are on Adjuvant therapy	**49**
Adjuvant Chemotherapy	**18**
Adjuvant AC	12
Adjuvant CMF	5
Adjuvant CAF	1
Adjuvant Hormonal therapy	**31**
Patients who are on NED therapy	**67**
NED Hormonal Tamoxifen	**64**
Patients who are Mets therapy	**119**
Mets. Chemotherapy	42
Mets. Hormonal therapy	56
Mets. Biological therapy	18
Mets. Other	3

MENOPAUSAL STATUS

No. of patients whose menopausal status is known at Diagnosis	**146**
Pre menopausal Status	64
Post menopausal status	79
No. of patients whose current menopausal status is known	**168**
Pre menopausal Status	44
Post menopausal status	123


PILOT A OUTREACH PROJECTIONS
PREVENTION
DIAGNOSIS
CLINICAL SERVICES
RESEARCH
SUPPORT GROUPS
BCCCP
BCEDP
Partnerships
Enaccion
CSC
SFGH

Revised Statements of Work

Statements of Work- CQI Core

Overall Objectives

- Finalize process and outcomes measures for the BCC
- Continue to evaluate current processes and identify those most in need of CQI intervention.
- Identify and implement process for elements of work that should be routine and consistent among practitioners, and those whose variation should be encourage and tested.
- Develop CQI instruments to track/assure that patients are given clinical information that is data driven and consistent with principles of evidence based medicine, but have the flexibility to make choices consistent with their values.
- Assure that the Breast Care Center continues to meet the patients needs.
- Provide feedback to individual providers (BCC staff) on their own activities relative to their peers and on all aspects of information available to the CQI group.

Specific Tasks for Year 2 (some tasks will roll over to year 3)

C1.1 Choose clinical and medical outcome measures to be used as the "report card" for the Breast Care Center. These measures must reflect the needs of the patients, the physicians, purchasers, health plans, and employers.
C1.2 Help establish patient navigator program
C1.3 Create a new follow up program
C1.4 Hold a patient forum to address the issues of quality according the patient
C1.5 Identify hierarchy of values of patients and providers
C1.6 Create questionnaires for staff and MDs to fill out regularly to identify areas where improvement is needed.
C1.7 Tracking and then improving on the time it takes to perform a wire localization procedure.
C1.8 Creating patient satisfaction surveys-coordination all surveys and activities

Informatics:
Statements Of Work/Quality Objectives For Year 2

Quality Objective	Outcomes Measures/Targets	Interventions/Tools
BCC computer systems are kept running 24 hours/ day, 7 days/week	Down time <10 minutes	Examine reasons for downtime and troubleshoot problems; develop diagram of all BCC computer systems, noting location and users
Minimal or no data are lost	Complete backup logs	Systems are backed up daily; create strict protocols for backup, preferably automated
Hardware and software meet UCSF open standards	100% of all applications	Standard open platforms; all purchases will be reviewed
Programmers code using standard style	All code corresponds to standards	Code reviewed and brought up to conforming standards; standards set by UCSF/Stanford
Programmers document code with comments and in manuals	All programs have documentation and manuals	Comments and manuals reviewed periodically
New and innovative concepts in automation are piloted and evaluated	Informatics support not limited to the standards that are available at the University, but the Informatics Core suggests innovative and new technology to support research efforts	Process improvement is supported through automated workflow software; the introduction of automation at the point of care enhances data collection and capture of patient clinical information
Structured data, data standards, and data elements are used and supported	Structured data are required to capture clinical information via automation and provide meaningful outcomes analysis	Consistent and standard data elements are defined
Data security is maintained	No security breaches occur	Appropriate use of software and hardware security tools, both at the operating system level, and through use of external tools such as routers and firewalls

Computer users receive appropriate support	Users' requests receive an initial response within 24 hours, and a final resolution within a reasonable time frame	A "help system" could be developed if necessary
Breast cancer data systems are linked to other research breast cancer systems and to clinical systems at UCSF, CPMC, Stanford, NCCC, etc.	Minimally, BCC systems are able to import/export data to/from other systems (Program Project, SPORE, PACE); ideally, systems can exchange data in real time	Common data elements for all breast cancer databases are developed where possible; interfaces are developed for all systems

(See next page for specifics.)

Specific goals and objectives for 1998 include:

1. Evaluation, further implementation, and expansion of the newly-implemented Lotus-based workflow system.

a. The Informatics Core will evaluate the new workflow system in partnership with front-office and clinical users. By interviewing current users, we will identify both the positive aspects of the system (usefulness, time-saving aspects, etc.) as well as its down side (bugs, confusing or erroneous design, etc.). As appropriate, we will continue to roll out the system to new users and train them.

b. The Informatics Core will work with Health Connection, the system developers, to insure that the system is fully functional per our contract, before "signing off" on the system. We will also insure that all documentation for system administrators and users is complete before the contract is considered satisfied.

c. The Informatics Core will develop a reporting system to extract data from the workflow system, to be used both in CQI projects, and in linkages with other systems (Breast Cancer Program Project, SPORE, PACE, NCCC, etc.).

2. Along the lines of *1a* above, the Informatics core will monitor and evaluate all other systems it implements or uses.

3. Per *1c* above, the Informatics Core will work with other breast cancer projects to develop common data standards and data elements to facilitate linkage of the various databases. We will give particular consideration to collecting standard data elements concerning such areas as physical exam, chemotherapy, follow-up (e.g., treatment status, disease status), etc.

4. The clinical trials system in current use will be developed to conform to *2.*. Consideration will be given to porting it to an SQL-based relational database system.

5. A simple system for capturing structured clinical data will be explored, including the use of mark-sense ("Number Two or softer pencil") forms.

6. A radiology database to include mammography and clinical data will be designed, taking into consideration similar databases at UCSF and Stanford.

7. Work on the BCC Web site will continue.

Education Core Revised Statements of Work: Year Two

The Education Core of the DOD sponsored grant revised the Statements of Work: Year Two in order to give the most comprehensive and updated summary of it's goals and objectives. This is based on our work from year one as well as experiences and feedback received during year two. We will continue to adapt these Statements of Work in order to provide the most effective educational programs for patients, staff, and the community.

Year Two

1. To establish an Education Core file cabinet to house patient information, professional literature bank, and information packets for newly diagnosed patients and biopsy procedures

2. To complete informational packets for patients undergoing TRAM flap surgery along with help of patient, physical therapy, anesthesia, surgical and nursing staff

3. To educate Breast Care Center staff about new patient education materials

4. To coordinate staff educational session about clinical aspects of breast cancer

5. To establish a community wide resource database with the Resource Center and other Bay Area cancer organizations

6. To continue offering Internet classes to patients and staff

7. To outline basic Internet usage guidelines in order to distribute to others (including patients, Resource Center, and other Cancer Center practices)

8. To increase resources/ patient education materials in the Resource Center

9. To highlight new resources with a "Book of the Month" program in the Breast Care Center

10. To work with Resource Center staff and DOD Grant Coordinator to highlight new resources in various newsletters

11. To coordinate resources for 7 week community wide art exhibit. The goal of the exhibit was to promote education and awareness about breast cancer

12. To sponsor an event for UCSF patients and staff as well as the community to support art exhibit and to increase awareness and education about breast cancer

13. To be involved with community events related to breast cancer, for example "Race for the Cure" and to provide educational materials at these events

14. To standardize resource materials for community outreach presentations

15. To document community outreach and evaluate the various types of outreach being offered

16. To provide informational materials for monthly community outreach sessions (Bay Area Breast Care Forums)

17. To compile a literature bank of the most pertinent articles related to breast cancer with help of Breast Care Center physicians

18. To build an online literature bank from computer searches of most recent literature and coordinate the online bank with the other articles in the Education Core File Cabinet

19. To initiate monthly information session for women who are newly diagnosed with breast cancer

20. To have State Guide Book translated into Russian

21. To have the pre and post operative orders translated into Russian

22. To gather information about self breast exams and other patient education information in foreign languages

23. To standardize the post-operative orders for surgical staff and residents

24. To develop Cancer Center Discussion Forum with Resource Center staff to bring in speakers once a month to discuss patient related issues

25. To develop a regular open house for patients based on successful model of community organization. Goal of open house is to provide support and to help answer questions

26. To start a Patient Navigator Program which includes training and support of volunteers and direct provision of educational support services to patients

Year Three

1. To work with Continuous Quality Improvement team to identify and implement clinical changes including those related to patient and provider education

2. To build information packets for patients about chemotherapy

3. To build information packets for patients about radiation therapy

4. To make an abbreviated list of the most pertinent articles from the literature bank for use by new surgical and medical residents, medical students, staff, and highly sophisticated patients

5. To translate the California State Guide booklet and pre/post op orders into Chinese

6. To assist with the coordination of the educational materials for clinical trials and translation to Spanish, Russian, and Chinese.

7. To write and review an information sheet on the new sentinel node biopsy procedure

8. To improve on tracking and evaluation of new and existing programs

Project 1 Revised Statements of Work

Aims / Tasks for Year 2 (some tasks will roll over to year 3)

Specific Aim 1
(This Aim has been significantly modified due to the merger of CPMC and UCSF Medical Groups, as described in last years Annual Report. Patients from these sites can now cross-sites and for this reason a comparison based on a comparison of the sites is no longer valid. Instead, we are sampling women from both sites, but the analysis will focus on differences in management by the primary care provider after the report of an abnormal mammogram. We will look at factors associated with differences in evaluation, timelines of resolution of the abnormal finding, patient satisfaction with their evaluation and the effect of evaluation on adherence with subsequent screening.)

For women with an abnormal mammogram, determine whether more coordinated care is associated with lower variation in the number and type of evaluative tests, more timely initiation of evaluation, fewer diagnostic tests, and shorter time to diagnosis of breast abnormalities compared to less coordinated care.

Specific Aim 2
Determine factors associated with differences in satisfaction with care among women being evaluated for abnormal mammograms.

Specific Aim 3
Determine whether the costs of care for women with more coordinated care are lower than the costs for women with poorer coordination of care.

Specific Aim 1. Coordination of Care

Task 1. Recruitment -- in progress; to be completed by October

Task 2. Survey Development -- questionnaires completed (see appendix)

Task 3. Clinical Information Systems
A computer database has been developed to abstract medical record information for each participating patient.

Task 4. Data Collection -- Surveys (in progress)

Specific Aim 2. Patient Satisfaction

Task 6. Questionnaire Development --see above.

Task 7. Data analysis
Overall scales of patient satisfaction, examining different aspects of care will be compared, including satisfaction with staff, communication with provider(s), understanding of tests, and levels of anxiety/quality of life. Women will also be specifically asked about loss of productivity and time lost from work related to their evaluations for breast abnormalities.

Aims 3 & 4
The patient satisfaction and the cost components of this project has been integrated into Aim 1 because of the merger of UCSF and CPMC. Data collection for these Aims was initiated in June, 1998.

Project 2
STATEMENT OF WORK

Task 1: Set up clinic for research, Months 1-3:
a. Hire secretary and social worker.
b. Purchase computer, printer, phones.
c. Ensure availability of group leaders.
d. Prepare assessment packets for patients to complete.
e. Ensure that physicians are aware of the psychosocial program.
f. Write information package describing the program and the interventions available.
g. Set up procedure for inputting data into database-coordinate with Informatics Core.

Task 2: Initial assessment and treatment of patients, testing of Aim 1, Months 4-16:
a. Begin patient entry into research program.
Assessment of women as they enter program.
b. Pilot data collection and intervention groups.
c. Conduct one-year follow up for all women in the program (assess psychological status, coping style and quality of life) in order to complete Aim 1.
d. Collect one-year medical data from data base in order to complete Aim 1.
e. Conduct follow-up assessments as the interventions are completed.

Year 2

Task 2: cont. : Year 2, Months 1-12
a. Pilot data collection and intervention groups.
b. Conduct one-year follow up for all women in the program (assess psychological status, coping style and quality of life) in order to complete Aim 1.
c. Collect one-year medical data from data base in order to complete Aim 1.
d. Conduct follow-up assessments as the interventions are completed.

Task 3: Initial statistical analysis, Month 6 (Also Year 3 and 4)
a. Perform analyses of data collected in Task 2 to address Aim 1.

Task 4: Testing Aims 2-3, Year 2-3
a. Add wait-list control groups (based on enough women participating). Begin to randomly assign women to immediate or wait-list groups.
b. Continue baseline and post-intervention assessments.
c. Continue yearly assessment of all women entered in the program.

Task 5: Final data analyses and write-up, Year 4.
a. Analyze data according to aims and hypotheses.
b. Results to be written and submitted for publication in journals and presentation at conferences.

Project 3:
Statements Of Work/Quality Objectives For Year 2

Project 3 has undergone major revisions since the submission of the progress report due to three factors:

1) Technical difficulties in operating the Videodisc program and accessory software and a lack of available equipment that can rusn the program properly
2) Outdated information in the Videodisc and major problems with the content from Bay Area advocacy focus groups
3) The availability of a new CD-ROM program described below which is much more flexible and will be completed in a timeline that will still allow enrollment of an adequate number of patients

This questionnaires and measures for this project are unchanged however.

The new CD-ROM will be jointly developed with Al Mulley and the development of this tool will be funded outside the DOD. We plan to revise the qualitative descriptions of risk and benefit as well as the testimonials. Estimates of baseline risk (recurrence and mortality) and adjuvant benefits (chemotherapy, hormonal therapy, both) will be provided from the Early Breast Cancer Trialists Group Overview. The benefits of patient subsets based on age and and ER status will be used for more precision and specificity when possible (enough patients in the subgroup such that the confidence interval is not very wide). We will attempt to obtain information on radiation therapy as it pertains to distant recurrence and mortality and include this if the data are sufficiently robust (specifically subsets that also received chemotherapy to see if the data from the recently published Danish and British Columbia trials are consistent with the Overview data). The patient questionnaires will be embedded into the program so that answers can be captured automatically. The CD-ROM can be configured to show specific portions such that information on "time gained" of recurence free and overall survival will be shown to half the patients as previously described. We plan to complete the CD-ROM and begin testing in 6-8 months. In order to compress accrual, we will partner with Marin Oncology, Northern California Kaiser, and Alta Bates. Given the advantage of CD-ROM technology, the much diminished time needed for data management and data entry, this will be possible.

Additions as of 11/17/97: Project III (refer to prior Outcome Measures)

Quality Objectives	**Outcomes Measures/Targets**	**Interventions/Tools**
Provide an understanding of the concept of average time gained (either free from recurrence or total survival) due to adjuvant therapy	Patient preferences for adjuvant therapy based on estimates of time gained	Assess value of a CD-ROM designed to convey individualized benefits and risks of adjuvant therapy for early stage breast cancer. Provide average time gained by adjuvant therapy to half patients (randomly assigned) and compare preferences between the two groups. Also assess subgroups based on age, education level, median income, stage, etc.

Category: Project III

Quality Objectives	Outcomes Measures/Targets	Interventions/Tools
Maximize the # of patients using a decision making tool for adjuvant therapy	Increase the ease of patient decision making for adjuvant therapy/90% of BCC patients view videodisk	Provide computer and database assisted risks of recurrence and death from early stage breast cancer
Maximize comprehension of a patient's risk of recurrence and death	Measure the perception of risk before and after patients view the videodisk and graphs/improve comprehension from 25% to 90%	Evaluate the videodisk and graphs:does the graph improve perception of risk?/questionnaires assessing patients' evaluation of the videodisk and graphs
Help patients make more informed decisions	Assess knowledge about the real benefit of adjuvant therapy/ perceived risk of recurrence and benefit of therapy is within 10% predicted	Provide computer and database assisted risks of recurrence and death from early stage breast cancer
Maximize the tracking of patients' therapy choices and medical follow-up	Measure the correlation between the decision make and medical outcome/95% BCC patients tracked	Physician completed forms entered into a database
Minimize the time between a patient's discussion of adjuvant therapy options with her oncologist and viewing the videodisk	Assess the time between medical oncologist visit and viewing of the videodisk/<2 weeks	Identify patients making adjuvant therapy decisions at weekly conferences
Improve patient satisfaction with decision making	Measure patient's satisfaction with their decision before and after patients view the videodisk and graphs/95% satisfaction with decisions	Provide computer and database assisted risks of recurrence and death from early stage breast cancer to help with decision making/questionnaires assessing satisfaction with the quality and quantity of knowledge received

Project 4 Revised Statements of Work

Task 1. Consultation Planning for Second Opinions

Consultation Planning is a visit preparation methodology invented during Year 1 of Project IV. The result of this preconsultation interview is a Consultation Plan, or flowchart showing what questions and concerns need to be addressed in order for the patient to be satisfied with the visit.

For Year 2 of Project IV, the first task will aim to extend the scope of Consultation Planning by solidifying the service in the Breast Care Center (BCC) and by directly involving physicians in the process. The following subtasks will be necessary:

Subtask 1: Consultation Planning for Second Opinions

- We will make this service available to all BCC patients scheduled for the tumor board.
- Physicians will use the plans to present patients concerns and questions for discussion at tumor board.
- By year three and four of the grant, we plan to have the personnel in place to offer Consultation Planning to all second opinions at the BCC. If possible, we will extend Consultation Planning Services to all BCC patients who desire them.
- We will coordinate the gathering of patient and physician psychosocial and cost outcomes with the appropriate BCC Core teams.

Subtask 2. Understand the issues surrounding decision making from the physician's perspective.

We are focusing initially on the multidisciplinary tumor board that convenes for second opinions.

- Communication Barriers e.g. tendency for physicians to state conclusions without giving their reasoning or pointing to published data, etc.
- Cultural Barriers e.g. tendency of physicians to get up in the middle of discussions to answer pages, etc.
- Structural Barriers e.g. no one is in charge of recording the discussion, no one is leading the meetings, etc.
- In years three and four we plan to expand the scope to explore all barriers experienced by physicians as they practice interdisciplinary care, not just at tumor board.

Subtask 3. Extend Consultation Planning techniques to capture discussion at tumor board and generate a Consultation Record of the proceedings.

- The Consultation Record will contain, in language the patient can understand, physician responses to the patient's concerns and questions as outlined in the Consultation Plan
- The Consultation Record will show the recommendations (consensus and points of difference) from various specialists and provide the reasoning and evidence (e.g. relevant clinical trial citations) for each.
- By year three and four we will then look to use the Consultation Record to generate a Treatment Plan for the patient and physician.

Subtask 4.

As we better understand the decision making needs for patients and their physicians, we will develop and test drive other methods and tools to support the decision making process. For example, adapting the Interaction Associates methods for *How to Make Meetings Work*.

Subtask 5.

Coordinate with other BCC Cores the assessment and comparison of health and cost outcomes of these interventions.

Task 2. Training Program for Consultation Planners

To ensure that Consultation Planning is established as a permanent, quality service at the BCC we are dedicated to developing a training program to teach others. The goal of the training program is to add to the skills set of participants who are already in defined roles at the BCC, e.g. nurses, resource center staff, and ultimately we aspire to recruit physicians. The training groups are based on an apprenticeship model, with an emphasis on skill building through practice. Currently, the group includes

- Dr. Jeff Belkora, the principal investigator for Project IV and largely responsible for the development of Consultation Planning;
- Karen Cushing, a doctoral candidate at Stanford, a trained Consultation Planner and the Research Assistant on Task 1;
- Stephanie Lamping, a doctoral candidate at Stanford, a trained Consultation Planner and the Research Assistant on Task 3; and
- Kristie Dold, a staffer at the UCSF Cancer Resource Center.
- Keren Stronach, a staffer in the UCSF Cancer Resource Center.
- Mimi Haberfelde, Breast Health Program coordinator at Marin General Hospital,
- Carole Pertofsky, Health Improvement Program Director at Stanford University;

The training program will be open to all interested and qualified UCSF staff, volunteers, and other breast cancer professionals in the Bay Area. The group meets weekly for two hours during which participants progress through each of the following stages of the process:

1. **Contracting** - We want to do everything possible to ensure that patients who need help overcoming barriers to communication receive our help, and that those who do not experience these barriers, do not.
   - Participants read the book *Spin Selling* and reflect on how we can ethically engage the patients in an exploration of their needs to determine whether Consultation Planning is a mutually beneficial next step.
   - We will spend several sessions role-playing the contracting portion of the intervention.
2. **Consultation Planning** - There is background reading necessary to understand the concepts and methods of Consultation Planning:
   - Consultation Planning articles describing the theory and methodology,
   - Decision Analysis focusing on key distinctions (e.g. materiality, relevance, operational decisions, strategic decision and tactical decisions),
   - Action Science focusing on productive advocacy and inquiry and intervention strategies to overcome barriers to communication (e.g. bypass, name, and engage), and

- Breast cancer, as in *Dr. Susan Love's Breast Book.*

3. **Consultation Planning Practice** - The best way to learn these skills is to practice, practice, practice:
   - Participants will start by observing others implementing consultation planning;
   - They will role play being the Consultation Planner in our practice group, and finally
   - as they become more familiar with the concepts and skilled in the techniques, they will try it on their own.
4. **Debriefing** - An important part of consultation planning and the training program is the debriefing stage. This is where we learn from the experiences in our group and with our clients.
   - During Consultation Planning sessions, planners will periodically check with clients and reflect on how things are going, how we are meeting their needs, and if not what we may do differently.
   - Similarly in our group sessions we will periodically articulate/reflect on what has happened, then critique it from different points of view so that we may redesign our actions as we proceed.

Task 3. Decision Modeling for Ductal Carcinoma in Situ (DCIS)

Many of the concerns expressed in Consultation Plans are from patients with Ductal Carcinoma in Situ who would like to avoid invasive therapy. Currently the lack of knowledge of the natural history of DCIS makes it impossible for medical specialists to offer a watchful waiting treatment alternative. However, the potential benefits of such an option to those patients diagnosed with DCIS warrant its consideration.
In order to evaluate this option, we will employ a computer simulation to get preliminary estimates on the percentage of DCIS tumors that will become invasive, on sub-groups of patients and tumors that are most at risk for progression, and on the expected length of the interval between diagnosis and invasion. The simulation is built on a mathematical model representing the progression of DCIS from a detectable stage toward invasion. The results from the simulation, if positive, will support the pursuit of clinical trials which include a watchful waiting arm.

1. The first phase of this task includes:
   - evaluation of problem feasibility and development of framework,
   - preliminary study of accepted treatment decision models and tumor progression analyses,
   - identification of potential data sources, and
   - development of preliminary DCIS growth models.
2. To build on promising results from the preliminary research, we propose to
   - iteratively develop, critique and refine DCIS growth progression models
   - evaluate data sources and design and conduct project specific pathology and/or mammography review if available data is unacceptable
   - use statistical data analysis for model parameter estimation
   - model analysis and output generation
3. If the progression model output is viable, then we plan to
   - develop a computer simulation of a clinical trial including the watchful waiting treatment arm
   - critique and refine the simulation

analyze the output as we run the simulation under various conditions

4. If the simulation indicates that a watchful waiting is a viable option for some patients, the results will be used to justify and design a prospective clinical trial.

There are several areas in breast cancer where uncertainty and unknowns are limiting options for patients. In the future, these methods can be used to collect and organize information about other decision alternatives for patients. For example, treatment alternatives for advanced stage disease where the costs to the patient are high, but the benefits are not always clear.

Summary

We believe these three tasks: *Consultation Planning for Second Opinions*, *Training Program for Consultation Planners*, and *Decision Modeling for DCIS*, will help us meet the needs of patients and physicians for decision support. As outlined, they will enhance the interdisciplinary care provided at the BCC through promoting improved patient and physician communication, increasing the skill set of BCC employees, and helping to introduce new alternatives for therapy and accurate information.

Pilot Project A:
Statements Of Work/Quality Objectives For Year 2

Pilot A project has now completed MD questionnaires (67 total) and preliminary analysis with plans to submit results to ASCO. Interesting differences of responses to clinical trial barriers are apparent based on physician's age, discipline, and setting of practice. All 150 patient questionnaires planned have now been collected and data entered. Data analysis is planned over the next month. Regular seminars for both patients and physicians regarding clinical trials are now in place. A website is in development with minutes of these meetings. Additionally, the website will provide a growing list of clinical trials, beiginning with those at UCSF, then expanded to the Bay Area (Collaboration w/ CTIP), and finally, a search engine will be developed for patient or physician use. We will keep up with developments at the NCI and their plans to revamp the PDQ clinical trials directory. New quality objective (see below) represents and enhanced outreach program to underserved and minority community in San Francisco and later the Bay Area. Separate funding will be needed source dedicated personnel will need to be engaged. Proposals will be submitted to Komen Foundation and California BCRP). We have identified Spanish and Russion speaking individuals suited for this job as these groups are the largest ethnic groups at SFGH and Mt. Zion.

Additions as of 11/17/97: Pilot A (refer to prior Outcome Measures)

Quality Objective	**Outcomes Measures/Targets**	**Interventions/Tools**
Improve patient access to information about clinical trials	Patient awareness / Reach 95% of BCC patients	Develop and distribute a monthly newsletter (also available on Website)
Inform minority individuals at risk or with breast cancer about clinical trials	Number of patients reached through outreach, number of calls received through hotline	Outreach programs to Latino, Russian, Chinese, and African American Community have been proposed and been submitted for funding

Additional measures available as of 1/12/98:

Number of total patients tracked since 7/97 as to type of visit and status of disease (all visits to BCC of patients with diagnosis of cancer) **613.**

Estimate of patients eligible for clinical trials **306** - [more precise determination pending]

Number of patients enrolled in treatment clinical trials - **9** (**3**% of eligible)

Category: Pilot A

Quality Objective	Outcomes Measures/Targets	Interventions/Tools
Maximize Enrollment in Clinical Trials	Increase # of Patients enrolled onto trials / from 5 to 12 % in year 1 compared to year 4 (pre/post intervention)	# of patients seen compared to # of patients eligible compared to # of patients enrolled
Maximize the identification of patients eligible for clinical trials	Track and match all patients at the BCC to eligible trials / 90% patients identified	Physician completed forms entered into a database
Improve patient access to information about clinical trials	Patient awareness / Reach 95% of BCC patients	• Conduct monthly forums for the community • Conduct meetings/information sessions in areas with low enrollment • Devise and support an Internet site that contains descriptions of all Bay Area clinical trials
Improve clinician access to information about clinical trials	Increase clinician awareness / Reach 100% BCC clinicians - 50% community breast oncologists	• Monthly caregiver conference/ review all open trials plus a discussion prior to opening any new trial • Display an updated list of clinical trials for physicians' reference
Increase enrollment onto clinical trials	Identify physician and patient barriers to enrollment to reduce barriers by 50% through intervention	• Questionnaire given to all breast cancer patients at the Breast Care Center • Questionnaire given to Bay Area breast cancer providers
Increase enrollment of minority women to clinical trials	Fewer barriers and more education to minority women about clinical trials/ Increased accrual of minority women onto trials from 3% to 12%	• Conduct community outreach to neighborhoods with low enrollment • Conduct education seminars for San Francisco General patients

DEPARTMENT OF THE ARMY
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REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y) 26 Aug 02

MEMORANDUM FOR Administrator, Defense Technical Information Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

FOR THE COMMANDER:

Encl

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